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3<sup>rd</sup> International Congress on

# ADVANCES IN CLINICAL RESEARCH AND TRIALS

**MARCH 21, 2023** 

**CLINICAL R&T 2023** 

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2023



### GMT - Greenwich Mean Time

08:45-09:00

**Opening Ceremony** 

### **Distinguished Speaker Talks**

Sessions: Clinical Research and Clinical Trials | Clinical Study Designs | Patient-Centric Clinical Trials | Innovations In Clinical Trials | Clinical Data Management and Statistics | Clinical and Medical Case Reports | Pharmacovigilance and Drug Safety | Drug Discovery and Development | Bioethics and Quality Regulation | Al In Clinical Trials | Digital Technology in Clinical Trials | Evidence-Based Medicine | Diagnosis of COVID 19

09:00-09:25	Title: Study on feasibility of the partial meniscal allograft transplantation Jiakuo Yu, Peking University Third Hospital, China				
09:25-09:50	Title: The efficacy and safety of brolucizumab for the treatment of nAMD: A systematic review and meta-analysis  Junian Chuan, Sichuan Academy of Medical Sciences & Sichuan Provincial People's Hospital, China				
09:50-10:15	Title: Retroviral vectorization for ex vivo gene therapy Xiaomo Wu, Dermatology Hospital of Fuzhou, China				
10:15-10:40	Title: Subclavian artery stenting via bilateral radial artery approach Tao Qiu, The first people's Hospital of Sichuan Province, China				
10:40-11:05	Title: Prediction and analysis of COVID-19 daily new cases and cumulative cases: Time series forecasting and machine learning models  Zehui Yan, China Medical University, China				
11:05-11:30	Title: Cure interrupted: Life and values during the HIV epidemic in Ethiopia Makoto Nishi, Hiroshima University, Japan				

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11:30-11:55	Title: Smart health care technologies to support computer aided diagnostics  Dhiraj Pandey, JSS Academy of Technical education, India					
11:55-12:20	Title: To evaluate the effect of change in end tidal carbon dioxide on optic nerve sheath diameter under general anaesthesia: A prospective study  Niraj Kumar, All India Institute of Medical Sciences, India					
12:20-12:45	Title: MECOM gene overexpression in pediatric patients with acute myeloid leukemia Mariam Elsherif, Children's Cancer Hospital Egypt, Egypt					
12:45-13:10	Title: Translational clinical trials in nutrition  Martin Kussmann, Kussmann Biotech GmbH, Germany					
	Lunch Break 13:10-13:40					
13:40-14:05	Title: Monitoring the ethical behaviour of conversational agents in healthcare domains Abeer Dyoub, University of L'Aquila, Italy					
14:05-14:30	Title: Automatic detection of potentially ineffective verbal communication for training through simulation Nicoletta Fossati, St George's University Hospitals, UK					
14:30-14:55	Title: Surgical options for mid-transverse colon cancer; A systematic review and meta-analysis Beshoy Effat Elkomos, Northwick Park Hospital, UK					
14:55-15:20	Title: Diabetes mellitus management in the context of cranial tumors Brandon Lucke-Wold, University of Florida, USA					
End of the Conference						
Closing Remarks						

Clinical R&T 2023 Scientific Program



### SCIENTIFIC ABSTRACTS

VIRTUAL EVENT

3<sup>rd</sup> International Congress on

# Advances in Clinical Research and Trials

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CLINICAL R&T 2023



# Advances in Clinical Research and Trials

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### Study on feasibility of the partial meniscal allograft transplantation

Jia-Kuo Yu<sup>1,2</sup>, Bao-Shi Fan<sup>1,2</sup>, Jing Ye<sup>1,2</sup>, Bing-Bing Xu<sup>1,2</sup>, Ze-Wen Sun<sup>3</sup>, Ji-Ying Zhang<sup>1,2</sup>, Shi-Tang Song<sup>1,2</sup>, Xin-Jie Wang<sup>1,2</sup>, Yi-Fan Song<sup>1,2</sup>, Zheng-Zheng Zhang<sup>4</sup> and Dong Jiang<sup>1,2</sup>

<sup>1</sup>Peking University Third Hospital, China <sup>2</sup>Institute of Sports Medicine of Peking University, China <sup>3</sup>The Affiliated Hospital of Qingdao University, China <sup>4</sup>Sun Yat-sen University, China

ince the meniscus is an important stabilizing structure of the knee joint and has a significant role in load-bearing and shock absorption, so the complete structural and functional reconstructions of the teared menisci should be done not only after partial meniscectomy but also post total meniscectomy. So far, animal experiments and good clinical practice have showed that the total meniscus allograft transplantation (TMAT) after total meniscectomy has partially solved the problem of structural and functional reconstructions after total meniscectomy. However, partial meniscectomy will also lead to accelerated knee degeneration, and its proportion is much higher than that of patients with total meniscectomy. Herein, the feasibility of partial meniscus allograft transplantations (PMAT) after partial meniscectomy was

investigated for the first time by using the 40% posterior horn meniscectomy model of the medial meniscus in Beagle dogs, and also for the first time, TMAT group and the total meniscectomy group were used as control groups. Compared with the TMAT, the transcriptomics evaluation, scanning electron microscope observation, histological regeneration and structure, biomechanical property, inflammation environment, and the knee function post PMAT were more similar to that of normal meniscus was first reported. This study provides a PMAT scheme with clinical translational value for the complete structural and functional reconstruction of the patients with partial meniscectomy and fills the gap in the field of teared meniscus therapy on the basis of quite well clinical applications of the meniscus repair and the TMAT

### **Biography**

Jia-Kuo Yu, PhD supervisor, director of the Institute of Sports Medicine of Peking University, director of the Department of Sports Medicine and Knee Surgery of Peking University Third Hospital. Studied in Germany as a senior visiting scholar between 1999 and 2001. Expert enjoying the special allowance of The State Council. Chairman of Geriatric Sports Medicine Branch of Chinese Society of Gerontology and Geriatrics. Group leader of Passive Implants of Medical Device Classification Technical Committee of State Drug Administration. Vice chairman of biomaterial advanced manufacturing branch of Chinese biomaterials Society. 99 English articles were published as the first author or corresponding author. 10 monographs of the chief editor or deputy chief editor. 66 patents have been granted (including 18 invention patents), 32 patents have been converted. The total amount of conversion exceeds RMB 100 million.



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# The efficacy and safety of brolucizumab for the treatment of nAMD: A systematic review and meta-analysis

### Junlan Chuan<sup>1,2</sup> and Liangiao Liu<sup>1,2</sup>

<sup>1</sup>Sichuan Academy of Medical Sciences & Sichuan Provincial People's Hospital, China <sup>2</sup>University of Electronic Science and Technology of China, China

**Introduction:** Brolucizumab can be used to treat neovascular age-related macular degeneration (nAMD) because it antagonizes vascular endothelial growth factor (VEGF) in the vitreous, as demonstrated in pivotal clinical trials. However, brolucizumab may cause retinal vasculitisobliterans in the presence of inflammation in the eyes. In the present study, a meta-analysis of randomized controlled trials (RCTs) was conducted to evaluate the efficacy and safety of brolucizumab.

**Methods:** Clinic Trail.gov., Embase, Cochrane library, Pubmed were retrieved from inception until December 31<sup>th</sup>, 2021 for RCTs assessing the efficacy and safety of brolucizumab. Changes in Best Corrected Visual Acuity (BCVA), and Central Sub-Field Thickness (CSFT), incidence of adverse events, serious adverse events and serious ocular adverse events were extracted from eligible RCTs. Meta-analysis was performed using Revman 5.4.1.

**Results:** Six RCTs with 3574 participants were finally involved in this meta-analysis. The changes of BCVA were not statistically significant different between brolucizumab treated group and aflibercept group. Brolucizumab induced higher CSFT reduction compared with control agent (aflibercept). The incidence of adverse events was similar between brolucizumab group and control group (OR 0.63, 95% CI 0.37 to 1.08, P=0.09), and brolucizumab caused less serious adverse events (OR 0.78, 95% CI 0.63 to 0.95, P=0.01). However, brolucizumab could lead to more serious ocular adverse events than lucentis and aflibercept (OR 2.15, 95% CI 1.11 to 4.16, P=0.02).

**Conclusion:** Brolucizumab was non-inferior to other anti-VEGF agents in improving BCVA and decrease CSFT. But it caused more serious ocular adverse events which is worthy of special attention by ophthalmologists.



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# Retroviral vectorization for ex vivo gene therapy

**X. Wu**Dermatology Hospital of Fuzhou, China

Pectorization of viruses provides the approach to exploit the remarkable viral capabilities of delivering genetic material to host cells. In the past decade, viral vector mediated gene therapy has emerged as a promising therapeutic modality for multiple inherited and acquired human diseases. Following just a single application, GT is capable of providing curative treatment or achieving long-lasting therapeutic benefits, which fundamentally distinguishes itself from traditional medicine. For the last four decades, retrovirus-based genetic intervention has been the major player in the field of GT, and multiple lentiviral/y-retroviral vector-mediated

GT products have been approved for treating various pathological conditions, immunodeficiency, blood disorders neurometabolic disorders. However, the early development of GT had been turbulent, with unexpected devastating effects exposed linked to the genotoxicities associated with retroviral semi-random genomic insertion. Here we talk about how the iterative vectorization processes taming the retroviruses, enabling them to become the foundation of modern gene therapy. And we will also take an evolutionary perspective to understand and perceive how retroviruses shaped us in the distant past.

### **Biography**

Dr. Xiaomo Wu is the head of Regenerative Medicine LAB and the deputy Director of the Dermatology Institute of Fuzhou, China. Wu received a B.A. in Medicine in 2002 from the University of Wuhan, followed by M.S. in Genetics in 2006 from the University of Fudan, Shanghai. In 2008, Wu came to Biozentrum, the University of Basel, Switzerland andreceivedPhD in Genetics in 2012 under Walter J. Gehring. She conducted her postdoctoral research in Bettler's LAB, Department of Biomedicine (DBM), also from the University of Basel, Switzerland. In 2017, Wu was recruited as a lad head and the deputy director of a newly founded institute in the Dermatology Hospital of Fuzhou, Fujian, China. In recent years, WU Lab has been dedicated to developing therapeutic interventions based on genetic modification and alteration, namely gene therapy, for treating multiple inherited skin diseases as well as some types of blood disorders.



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# Subclavian artery stenting via bilateral radial artery approach

Tao Qiu, Shenqi Fu, Xiong yong Deng, Ming Chen and Xiaoyan Dai

The first people's Hospital of Sichuan Province, China

**Background:** Subclavian artery stenosis refers to the stenosis in the lumen caused by the presence of plaque or thrombus in the subclavian artery. It is a common problem in endovascular interventions. In fact, conventional subclavian artery stenting via the femoral artery approach is effective and safe. Nevertheless, because femoral artery puncture is not easy to stop bleeding, it requires longer femoral artery compression or more expensive hemostatic materials, such as staplers. Patients need to be catheterized and bedridden for a longer time, which may lead to

many complications, such as pseudoaneurysm.

**Method Summary:** We report a new subclavian artery interventional therapy. Through the bilateral radial artery approach, the 5F radial artery sheath was inserted on the opposite side of the lesion, and the 5F SM2 contrast tube was used for imaging positioning. The 6F radial artery sheath was inserted on the side of the lesion, and the guide wire was used to directly guide the stent to the subclavian stenosis without using the guide tube.







**Conclusion:** Reviewing the successful placement of clavicular artery stents through bilateral radial arteries in our center, we believe that bilateral radial artery approach is feasible.

Clavicular artery stenting is safe, effective and time-saving. It is an excellent alternative to traditional femoral artery surgery, with few complications and high comfort.



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### **Biography**

Qiu Tao, deputy chief physician, MD, master's supervisor, director of Neurology Department of Zigong first people's hospital. He studied in Italy in 2017. Member of the transradial interventional cooperative group of the Neurointerventional branch of the Chinese Research Hospital Association; Vice chairman of the Special Committee on nerve intervention of Sichuan society of traditional Chinese medicine; Vice chairman of stroke prevention and Treatment Society of Sichuan medical communication society. Reviewer of frontiers in bioscience landmark and Journal of clinical neurology. He is mainly engaged in the clinical and research work of ischemic cerebrovascular disease and nerve intervention. In 2009, he took the lead in conducting cerebrovascular intervention diagnosis and treatment in Zigong. It won two second prizes of new technology of Zigong health system. It has made 5 scientific and technological progress in Zigong. He has published 8 SCI papers, edited 2 monographs and won 2 national patents.



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Prediction and analysis of COVID-19 daily new cases and cumulative cases: Time series forecasting and machine learning models

Zehui Y<sup>1</sup>, Yanding W<sup>1,2</sup>, Ding W<sup>3</sup>, Meitao Y<sup>1,2</sup>, Zhiqiang L<sup>1,2</sup>, Xinran G<sup>1,2</sup>, Di W<sup>1,2</sup>, Lingling Z<sup>1</sup>, Wenyi Z<sup>2</sup> and Yong W<sup>1,2</sup>

<sup>1</sup>China Medical University, China

**Background:** COVID-19 poses a severe threat to global human health, especially the USA, Brazil, and India cases continue to increase dynamically, which has a far-reaching impact on people's health, social activities, and the local economic situation.

**Methods:** The study proposed the ARIMA, SARIMA and Prophet models to predict daily new cases and cumulative confirmed cases in the USA, Brazil and India over the next 30 days based on the COVID-19 new confirmed cases and cumulative confirmed cases data set(May 1, 2020, and November 30, 2021) published by the official WHO, Three models were implemented in the R 4.1.1 software with forecast and prophet package. The performance of different models was evaluated

by using root mean square error (RMSE), mean absolute error (MAE) and mean absolute percentage error (MAPE).

**Results:** Through the fitting and prediction of daily new case data, we reveal that the Prophet model has more advantages in the prediction of the COVID-19 of the USA, which could compose data components and capture periodic characteristics when the data changes significantly, while SARIMA is more likely to appear over-fitting in the USA. And the SARIMA model captured a seven-day period hidden in daily COVID-19 new cases from 3 countries. While in the prediction of new cumulative cases, the ARIMA model has a better ability to fit and predict the data with a positive growth trend in different countries(Brazil and India).

<sup>&</sup>lt;sup>2</sup>Chinese PLA Center for Disease Control and Prevention, China

<sup>&</sup>lt;sup>3</sup>Beijing University of Posts and Telecommunications, China



# Advances in Clinical Research and Trials

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# Cure interrupted: Life and values during the HIV epidemic in Ethiopia

M. Nishi
Hiroshima University, Japan

his presentation examines how the pharmaceutical-driven model of public health has altered forms of HIV care in Ethiopia during the past decade. First, it examines how the efforts to "cure" the lives of some people affected by HIV have been marginalized through the process that some medical anthropologists referred to as the exercise of "triage." Second, it considers how the process was facilitated by narrowly defined concepts of life and value in mainstream global health discussions by comparing them with the anthropological theory of values.

In my ethnographic research in a provincial town in Ethiopia, I examined how the expansion of the antiretroviral treatment program interplayed with local actions through which suffering inflicted by the epidemic was cared for 1 Local health institutions served the town's population by disseminating antiretrovirals

free of charge. However, they referred patients whose problems were too complicated to be solved by the drugs to a local association of people with HIV. I regarded this as an exercise in "triage" because the association was systematically deprived of the resources required to address its members' needs.

Pharmaceutical agents are valuable because of their power to improve life. However, what it means to "make life better" needs clarification. Medical anthropological theory assumes that for all living entities, value arises from life, meaning the value is always embodied. The embodied value enhances life to become more relevant to its social and biological environments. However, healthcare theories and practices that do not entertain embodied values fall short of "curing" the lives of persons.

#### **Biography**

Makoto Nishi is an associate professor at the Graduate School of Humanities and Social Sciences, Hiroshima University. His current research projects focus on biosocial etiologies of some neurological conditions, including parasite-induced epilepsy in post-conflict northern Uganda and autism during the COVID-19 pandemic in Japan.



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## Smart health care technologies to support computer aided diagnostics

### **Dhiraj Pandey**

JSS Academy of Technical education, India

ardiovascular diseases (CVD): Now a day's number one cause of death. The mortality rate due to CVD is around 272 person per lakh in comparison to 235 per person globally. ECG is commonly used signal to detect it for initial findings. Several approaches based on wavelet-based variants on ECG are studied to detect coronary artery diseases and helping the computer aided diagnostic system. Apart from ECG, EEG test is very much popular to detect any brain activity disorder. EEG signals are also used in Brain-computer interfaces (BCIs).

Detecting early any diseases or any brain disorder may help us to save lives of several

people who commits suicide (eg. Farmers). In this talk, major discussion will be based on how Deep learning-based approaches can be used to improve the diagnosis task. The task primarily consists of two sub problems. First part of the discussion will be focused on identification of abnormal cases, i.e., whether the brain contains any symptoms or not. In the second part classification of the type will be discussed in details. Automatically categorizing the diseases type is a relatively more challenging task comparing to the binary classification of normal and abnormal personal and convolutional neural networks are found to be very successful in biological tasks.

### **Biography**

Dr. Dhiraj Pandey received his Ph.D. in Computer Science and Engineering from Manipal University in August 2018. He received his B.Tech degree in Information Technology in the year 2003 and an M.Tech degree from the University School of Information Technology, GGSIPU, New Delhi in the year 2007. He has more than 19 years of rich academic experience. He joined the Department of Computer Science and Engineering at JSS Academy of Technical Education Noida in January 2011 and currently working as Associate Professor there. His recent research interests include assistive technologies, image processing, and information security allied areas. He is a Senior Member of IEEE. He has published more than 40 papers in SCI/Scopus indexed Journals and Conferences.



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# To evaluate the effect of change in end tidal carbon dioxide on optic nerve sheath diameter under general anaesthesia: A prospective study

Niraj Kumar<sup>1</sup>, Rashmi Mahapatra<sup>2</sup>, Gyanindra Pal singh<sup>1</sup>, Ashish Bindra<sup>1</sup> and Keshav Goyal<sup>1</sup>

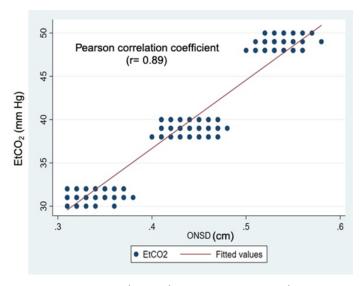
<sup>1</sup>All India Institute of Medical Sciences, India <sup>2</sup>Indraprashtha Apollo Hospital, India

**Objectives:** Primary objective: To evaluate the change in optic nerve sheath diameter (ONSD) with change in end tidal carbon dioxide (EtCO<sub>2</sub>). Secondary objective: To evaluate if the change in ONSD in response to change in end tidal carbon dioxide is immediate (real time). To evaluate if the change in ONSD is reversible with restoration of end tidal carbon dioxide to previous level.

**Scope:** Elevated intracranial pressure (ICP) is a common and potentially life-threatening condition. The trans-orbital ultrasonography, is a non-invasive method which detects raised ICP by evaluating increases in the optic nerve sheath diameter (ONSD). Dynamic

responsiveness of ONSD, in association with acute change in EtCO<sub>2</sub>, (both hypercapnia and hypocapnia) which can affect ICP, still has not been well investigated. We hypothesized that there would be dynamic changes in ONSD in response to corresponding changes in EtCO<sub>2</sub>.

**Results:** A strong correlation was found between the corresponding EtCO<sub>2</sub> and ONSD values with Pearson's correlation coefficient of 0.89(fig -1). There was no statistical difference between ONSD values at 0 and 5 minutes after attaining the desired EtCO<sub>2</sub> level. The change in ONSD were reversible with EtCO<sub>2</sub> reversibility.



*Figure-1:* Correlation between ONSD and EtCO.



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**Methods:** 56 patients, with age between 18-60 years, either sex, and admitted to undergo elective spine surgery under general anaesthesia were included. All patients were exposed to both hypercapnia and hypocapnia and the ONSD values were recorded. However, for the purpose of the study, after induction of GA the respiratory rate was adjusted to

attain the desired  ${\rm EtCO_2}$  value (normocapnia, hypocapnia or hypercapnia). ONSD values were obtained at normo-, hyper- and hypocapnia in all the patients.

**Conclusion:** ONSD has a strong correlation with  $EtCO_2$  and it changes directly and significantly in response to changes in  $EtCO_2$ .

### **Biography**

Niraj Kumar is a professor in the Department of Neuroanesthesiology and critical care, at Aiims, New Delhi. He is actively involved in conducting Research projects (e.g., Intramural, extramural, DM thesis). He has developed novel pressure measuring device for the ultrasound probe with AIIMS –IIT Delhi collaborative project (as Principal investigator), the device is under the patent process. He has completed a fellowship Program: (Clinical Research Methodology and Evidence-Based Medicine) at AIIMS, New Delhi. He is the instructor (Faculty) of –ATLS, ANC, ACCC, AIIMS – EM-SONO, AUTLS, AIIMS cadaver airway. He is the Course Director of - Cadaveric Airway Management Course. He has delivered a series of talks in ultrasound as Course Director - Ultrasound POCUS SERIES - Classroom "an online ISNACC initiative. He has given a series of lectures in the National Live Webinar Series -Neuroanesthesia, conducted by NBEMS (National board of examinations in Medical Sciences).



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# MECOM gene overexpression in pediatric patients with acute myeloid leukemia

Mariam Elsherif<sup>1</sup>, Mahmoud Hammad<sup>1,2</sup>, Hanafy Hafez<sup>1,2</sup>, Dina Yassin<sup>1,2</sup>, Mohamed Ashraf<sup>1</sup>, Nouran Yasser<sup>1</sup>, Leslie Lehmann<sup>3</sup> and Alaa Elhaddad<sup>1,2</sup>

<sup>1</sup>Children's Cancer Hospital Egypt (CCHE), Egypt

**Background:** Acute myeloid leukemia (AML) is characterized by blocked or aberrant differentiation of hematopoietic stem cells. The *MECOM* gene overexpression in hematopoietic progenitors induces myeloid differentiation block, resulting in increased self-renewal and survival of these transformed progenitors. However, its exact role in AML remains unclear. We aimed to estimate the prevalence of *MECOM* over expression among pediatric AML patients, and assess its impact on clinical outcome.

**Patients and Methods:** Real-time quantitative polymerase chain reaction and Livak method  $(2\Delta\Delta Ct)$  were used to determine relative *MECOM* expression level among 243 pediatric patients with AML. *MECOM* overexpression was considered if the cumulative relative expression was above 1  $(2^{-\Delta\Delta Ct})$  and was designated as *MECOM*<sup>pos.</sup>

**Results:** Of 243 AML patients tested 57 (23.5%) demonstrated *MECOM*<sup>pos</sup>. Patients with *MECOM*<sup>pos</sup> had significantly lower median age. The frequency of *MECOM*<sup>pos</sup> was significantly higher among AML patients with 11q23 abnormalities, complex karyotypes and among

high- and intermediate-risk groups compared to low-risk group (P=0.014). MECOMpos patients had significantly lower overall survival (OS) (38.7 vs. 78.9%, P<0.001), event-free survival (EFS) (37.3% vs. 68.4%, P<0.001), and had higher cumulative incidence of relapse (49.5% vs. 23.5%, P=0.002) at 36 months compared to MECOMneg patients. Multivariate analysis revealed that MECOMpos was an adverse prognostic factor for OS (hazards ratio (HR) = 2.11, 95% confidence interval (CI) 1.24–3.60, P=0.006) and EFS (HR= 1.71, 95% CI 1.07-2.75, P=0.025). The logistic regression model showed that MECOMpos was an independent prognostic factor regardless of minimal residual disease status post first induction therapy in the intermediate-risk group (odds ratio 2.89; 95% CI 1.19-6.57, P=0.018).

**Conclusion:** The aberrant *MECOM* gene expression is an adverse prognostic factor, especially in patients without previously known cytogenetic risk factors. Our results suggest the potential benefit from pre treatment screening for *MECOM* gene over expression in newly diagnosed AML patients for better risk stratification and treatment adjustment.

<sup>&</sup>lt;sup>2</sup>Cairo University, Egypt

<sup>&</sup>lt;sup>3</sup>Dana Farber Cancer Institute, USA



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### **Biography**

Mariam Elsherif is a consultant of paediatric oncology at the Children's Cancer Hospital "CCHE, 57357". Following her graduation from the Faculty of medicine, Ain Shams University in 2009, she started her residency at the department of paediatrics Ain Shams University" where she got her Master Degree in general paediatric in 2014 and subsequently completed my fellowship in Paediatric Hematology/Oncology CCHE and Dana Farber/Boston Children's Hospital USA, in conjunction with earning my Doctorate degree in Paediatric Oncology from the National Cancer Institute, Cairo University.



# Advances in Clinical Research and Trials

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# Translational clinical trials in nutrition

#### M. Kussmann

Head of Science, Competence Center for Nutrition (KErn), Germany CEO and Founder, Kussmann Biotech GmbH, Germany

linical trials in nutrition should explore, test, and validate nutritional solutions to maintain and improve human health. These solutions can come in the form of (micro-)nutrients, bioactives, (functional) ingredients, diets, or supplements. They can address digestive, metabolic, endocrine, immune, cardiovascular, muscle/bone and cognitive health1.

To render these trials more comparable and translational, traditional, and often non-standardized study designs must be complemented by clinical studies featuring the following characteristics:classical RCTs with group-average comparisons must be complemented by longitudinal, or (nested) n-of-1 studies, in which every subject is its own case and control; enrolled subjects should be clinically and molecularly phenotyped; administered diets, especially when applied under specific terms, should be clearly defined and described; intervention studies

should apply safe, well-defined nutritional inputs or challenges and probe the elasticity of the human metabolic system in addition to sampling at homeostasis2,3.

Interventions can be better informed and designed upfront by bioinformatics artificialintelligence:considering molecular mechanisms of e.g.metabolic, digestive, or immune health, the biological effects of ingredients (micronutrients, bioactive phytonutrients, pre-/probiotics, bioactive peptides) can be either computationally retrieved from existing literature4, or -to some extent- predicted in silico, thereby limiting the number of compounds or ingredients to be tested5. The best sources for those targeted functional nutritional compounds can be identified by computational mining of the genomes, metabolomes, and proteomes/ peptidomes of e.g. plants and foods6, thereby fostering both healthy and sustainable diets7.

### **Biography**

Dr. Martin Kussmann was trained as a biochemist and has accomplished a thirty years' dual corporate/academic career with experience in nutrition, pharma, and biotechnology. He held professorships at EPF Lausanne, Switzerland; Aarhus University, Denmark; and Auckland University, New Zealand, where he was also Scientific Director of the National Science Program on Food Innovation. Kussmann spent thirteen years at Nestlé Research as Department Head and Primary Investigator. He has co-created and managed four research units and scientifically led two institutions. His research focuses on translational human studies in nutrition and health, multi-omics biomarker development, and artificial intelligence-enabled discovery and validation of natural bioactives. Kussmann is an internationally requested multi-lingual author, editor, and lecturer credited with ~150 publications, >30 media/press communications, and numerous presentations.



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# Monitoring the ethical behavior of conversational agents in healthcare domains

**Abeer Dyoub**University of L'Aquila, Italy

onversational Agents (CA) are artificial intelligent software which can simulate a conversation with a user in natural language via auditory or textual methods. They are some of the industry's newest tools designed to simplify the interaction between humans and computers. From a technological point of view, a CA only represents the natural evolution of question answering system leveraging Natural Language Processing and Understanding. In 2020, tele-health experienced an unprecedented uptake around the globe, with the COVID 19 pandemic acting as a catalyst. The COVID-19 pandemic

accelerated the introduction of virtual healthcare delivery in many countries, it also prompted the rapid development of many other diverse technology-enabled systems and processes for delivering virtual healthcare to patients. One new technology development is the widespread uptake of conversational agents in people's lives, and these now also have many health applications.

Despite the potential benefits of the technology, CA raise many ethical concerns. In this talk, I discuss ethical concerns of CA in healthcare domains in general and then present a proposal for monitoring the ethical behavior.

### **Biography**

Abeer Dyoub is assistant professor at the Department of Engineering, Computer Science and Mathematics (DISIM), University of La'Aquila. Her research interest focuses on Artificial Intelligence, with special focus on Computational Logic including Intelligent Agents and Multi Agent Systems, Knowledge Representation and Reasoning, Interpretable Machine Learning, and Machine Ethics. She is a fellow of ACM, GRIN, AIXIA, and GULP. She holds a bachelor's degree in electronic engineering from Tishreen University, Syria 2000, a master's degree in computer science 2004 from JMI university, India, and a PhD in ICT from the University of L'Aquila, Italy, 2019.



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# Automatic detection of potentially ineffective verbal communication for training through simulation

Gianpaolo Coro<sup>1</sup>, Serena Bardelli<sup>2</sup>,

Armando Cuttano<sup>2</sup> and Nicoletta Fossati<sup>3</sup>

<sup>1</sup>Istituto di Scienza e Tecnologie dell'Informazione "A. Faedo", Consiglio Nazionale delle Ricerche, via Moruzzi 1, 56124 Pisa, Italy

<sup>2</sup>Centro di Formazione e Simulazione Neonatale, Azienda Ospedaliero-Universitaria Pisana, via Roma 67, 56126 Pisa, Italy

<sup>3</sup>St George's University Hospitals, Blackshaw Road, SW17 0QT London, United Kingdom

**Objectives:** Artificial Intelligence models can extract human-factor related information from audio recordings. We present an automatic workflow detecting dialogue segments with potentially ineffective communication between team members during neonatal simulation sessions.

Materials and Methods: 10 cases from historical audio recordings of neonatal simulation training sessions at Centro NINA, Maternal-Neonatal Department, Azienda Ospedaliero Universitaria Pisana (Pisa, Italy) were selected. The workflow analysed syllabicscale (100-200 ms)spoken dialogue energy and intonation, using cluster analysis based on the K-means algorithm1. Tone units were detected, their audio segments extracted and, through cluster analysis of energy and pitch, labelled as either potentially ineffective or viable verbal communication. The audio of potentially ineffective units was transcribed through an automatic speech recogniser, and keywords extracted to produce a word cloud. Performance was measured against a gold standard containing annotations of 79 minutes

of audio recordings from neonatal simulations, in Italian, under different noise conditions (from 4.63 to 14.17 SNR), compiled by two researchers with complementary expertise in the field.

**Results:** Our workflow achieved a detection accuracy of 64% against a commercial automatic speech recogniser sentence accuracy of 9.37%. Detected keyword viability - the percentage of gold-standard words contained in the word cloud - was 59%. Potentially ineffective communication keywords included repeated items in the first person plural, and expressions of uncertainty, which may point toissues around leadership, self-confidence, and/or instruction clarity. There was no reference to time or equipment/setting issues.

**Conclusion:** Our workflow successfully identified effective/ineffective communication during neonatal simulation sessions. It can be applied to other languages than Italian and can help trainers refine feedback and measure learning improvement.



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### **Biography**

Dr. Nicoletta Fossati with a medical degree and a PhD, both from Pisa University and S. Anna School of Advanced Studies, complemented by a specialty degree in Anaesthesia and Resuscitation, She has held a consultant level job in Italy for 10 years before moving to London in 2004 to take on a Consultant Anaesthetist post at St George's Hospital.

In addition to anaesthesia, she has a long-standing interest in medical education. An Honorary Reader in Clinical Education and Anaesthesia at St George's, University of London, she holds a Master's degree in Higher and Professional Education (Institute of Education/UCL). In July 2022 she was awarded the Senior Fellowship of Advance HE/Higher Education Academy (SFHEA).



# Advances in Clinical Research and Trials

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# Surgical options for mid-transverse colon cancer; A systematic review and meta-analysis

Beshoy Effat Elkomos<sup>1</sup>, Safa Owhida Baqar<sup>1</sup>, Muhammad Faran Raza Bhatti<sup>1</sup>, Sameh Ahmed<sup>1</sup>, Abdirahaman Nuno<sup>1</sup>, Meenakshi Jhala<sup>1</sup>, Muhammad Mazhar<sup>1</sup>, Muddasir Hassan<sup>1</sup>, Joseph Hanna<sup>2</sup>, Guirgis Boushra Ebeidallah<sup>3</sup>, Philopateer Effat Ellomos<sup>4</sup> and Mina Fransawy Alkomos<sup>5</sup>

<sup>1</sup>Northwick Park Hospital, London NorthWest University Healthcare NHS Trust, UK

**Background and Aim:** The incidence of cancer colon below the age of 50 has increased dramatically. in addition, the database lacks a review to analyze the outcomes of surgeries for mid-transverse colon cancer with several recent controversial studies. Our aim was to compare the outcomes of extended hemicolectomy versus transverse colectomy for mid-transverse colon cancer.

**Method:** PubMed, Scopes, Web of Science and Cochrane library were searched for eligible studies from inception to 1 May 2022 and a systematic review and meta-analysis were done to detect

**Results:** According to eligibility criteria 8 studies (2237 patients) were included in our study. The pooled results of the included studies showed no difference in the 5-year OS,

3-year DFS and 5-year DFS between the two types of surgery (5-year OS, RR = 1.15, 95% CI = 0.94-1.39, P = 0.17), (3-year OS, RR = 0.96, 95% CI = 0.88-1.06, P = 0.42) and (5-year DFS, RR = 1.21, 95% CI = 0.91-1.62, P = 0.20). In addition to that, the recurrence rate and the incidence of complications were similar in the two groups (Recurrence rate, RR = 1.08, 95% CI = 0.62-1.89, P = 0.79) and (Complications, RR = 1.07, 95% CI = 0.74-1.54, P =0.72). However, the number of LN harvest and the time of the operation was more in case of extended hemicolectomy.

**Conclusion:** Despite harvesting less LN, transverse colectomy has similar oncological outcomes to extended hemicolectomy for mid-transverse colon cancer. Moreover, no significant difference in the incidence of complications.

### **Biography**

Beshoy Effat Elkomos is having 3 years experience as a surgical resident the at general surgery department, Ain sham university hospital. He is currently working at the general and emergency department, Northwick park hospital, LNWH NHS.

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<sup>&</sup>lt;sup>3</sup>University Hospitals of Derby and Burton NHS Foundation Trust, UK

<sup>&</sup>lt;sup>4</sup>Ain Shams University Hospital, Egypt

<sup>5</sup>St. Joseph's University, USA



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### Diabetes mellitus management in the context of cranial tumors

Brandon Lucke-Wold
University of Florida, USA

he study of the relationship between cancer and diabetes mellitus (DM) has been under investigation for many decades. Particularly in the field of neurology and neurosurgery, increasing emphasis has been put on the examination of comorbid DM in patients with cranial tumors. Namely, as the most common and invasive type of malignant adult brain tumor, glioblastoma (GBS) has been the focus of said research. Several mechanisms have been described in the attempt to elucidate the underlying association between DM and GBS, with the metabolic phenomenon known as the Warburg effect and its consequential downstream effects serving as the resounding culprits in recent literature. Since the effect seen in cancers like GBS exploits an upregulated form of aerobic glycolysis, the role of a sequela of DM, known as hyperglycemia,

will be investigated. In particular, in the treatment of GBS, surgical resection and subsequent chemotherapy and/or radiotherapy are used in conjunction with corticosteroid therapy, the latter of which has been linked to hyperglycemia. Unsurprisingly, comorbid DM patients are significantly susceptible to this disposition. Further, this fact is reflected in recent literature that demonstrates the impact of hyperglycemia on cancer advancement and patient outcomes in several preclinical and clinical studies. Thus, this review will aim to underline the significance of diabetes and glycemic control via standard-of-care treatments such as metformin administration, as well as to describe emerging treatments such as the signaling modulation of insulinlike growth factor and the employment of the ketogenic diet.

#### **Biography**

Brandon Lucke-Wold was born and raised in Colorado Springs, CO. He graduated magna cum laude with a BS in Neuroscience and distinction in honors from Baylor University. He completed his MD/PhD, Master's in Clinical and Translational Research, and the Global Health Track at West Virginia University School of Medicine. His research focus was on traumatic brain injury, neurosurgical simulation, and stroke. At West Virginia University, he also served as a health coach for the Diabetes Prevention and Management program in Morgantown and Charleston, WV, which significantly improved health outcomes for participants.



### ACCEPTED ABSTRACTS

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### **Advances in Clinical Research and Trials**

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### The effect of ZnO NPs on genotoxicity and cell death using the optimum dispersion solution of breast cancer cell lines MCF-7

A. El Sadiegue<sup>1,2</sup>, M. Shawki<sup>1</sup>, S. Elabd<sup>1</sup> and M. Moustafa<sup>1</sup>

<sup>1</sup>Alexandria University, Egypt <sup>2</sup>Alexandria University Cancer Research Cluster, Egypt

owever, the number of in vitro studies are being published regarding the cytotoxicity of nanomaterials is on the increase, the components of the media for toxicity assays have often varied according to the needs of the scientists. Our aim for this study was to: (1) evaluate the influence of serum-in this case. fetal bovine serum FBS, Phosphate Buffer Saline PBS, water for injection, without fetal bovine serum FBS, in a cell culture medium on the toxicity of nano-sized (20-30 nm) ZnO on human breast cancer cell line (MCF-7) and (2) use very small dose that make 50% of cancer cell death after treatment in order to the normal cells can get rid of it and be safe on body normal cells. (3) by using the optimal disersion solution: studying the genotoxicity of ZnO NPs on MCF-7. Dispersion solution is effective factor of cell viability in presence of ZnO NPs as a treatment. The nano sized ZnO

exhibited their highest toxicity when exposed to Phosphate buffer saline, in contrast to exposure in media containing 10% serum. This mainly comes from the absence of protein protection, and lower cell growth rate, but also that when we used sterilized water for injection as the dispersion solution it has an observed toxicity and a negative osmotic effect on cells that make cells increase till exploding. So when we used media FBS free as a dispersion solution the toxicity of ZnO NPs is nearly the same of PBS which made us recommended using media FBS free as an optimum dispersion solution that has a great effect on DNA strand breaks in eukaryotic cells using comet assay; DNA damage that representing with the comet tail confirm the ability of ZnO NPs not of cancer cell death only but for disturbance the proliferation by its genotoxicity effect.



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effect of PBAT on plant growth \$9

### Agsa kanwal, Min Zhang, Faisal Sharaf and Chengtao Li

Shaanxi University of Science & Technology, China

he globe is facing increasing challenges of plastic pollution due to single-use of plastic-based packaging material. The plastic material is continuously being dumped into the natural environment which causes serious harm to the entire ecosystem. Polymer degradation in nature is very difficult, so the use of biodegradable polymers instead of conventional polymers can mitigate this issue. Due to the good mechanical properties and biodegradability, aliphatic-aromatic polymers are being widely commercialized. Due to the advancement in molecular biology, studies have reported specific microbes that can effectively degrade PBAT. Aliphatic polyesters undergo hydrolytic cleavage of ester groups, so they can be easily degraded by microorganisms. In this study, we investigated the enzymatic degradation of poly (butylene adipate terephthalate) (PBAT) copolymer using lipase B from Candida Antarctica (CALB). Results of the study displayed approximately 5.16 % loss in PBAT mass after 2 days which

significantly increased to approximately 15.7 % at the end of the experiment (12 days) as compared to blank. The pH of the degradation solution also displayed significant reduction and reached the minimum value of 6.85 at the end of the experiment. The structure and morphology of PBAT after degradation were characterized by FTIR, XRD, SEM, and TGA.FTIR analysis showed that after degradation many peaks become weaker and the peak at 2950 cm-1 almost disappeared after 12 days. The XRD results indicated that as the degradation time increases the intensity of diffraction peaks slightly increases as compared to the blank PBAT. TGA analysis also confirmed the successful degradation of PBAT with time.SEM micrographsfurther confirmed that degradation has occurred. Hence, biodegradable polymers can widely be used. The effect of PBAT biodegradation on plant growth was also studied and it was found that PBAT has no toxic effect on the growth of plants. Hence PBAT can be employed in a wide range of applications.



## Advances in Clinical Research and Trials

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# Spirometry as a motivator for smoking cessation among patients attending the smoking cessation clinic of Monastir

### Behaeddin Garrach<sup>1</sup>, Menel Ben Fredj<sup>2</sup> and Belguith Sriha Asma<sup>2</sup>

<sup>1</sup>Faculty of Medicine of Monastir, Tunisia

<sup>2</sup>Department of epidemiology and preventive medicine of the university hospital Fattouma Bourguiba, Tunisia

**Background:** The choice of spirometry, a biomarker of lung health, as a motivator for smoking cessation is based on its fidelity in emphasizing tobacco adverse effects. Yet, there is a paucity of evidence on its efficacy, and the findings are currently inconclusive.

The aim of this study was to determine whether a spirometry and lung age communication has an effect on smoking cessation rates.

**Methods:** We conducted a randomized controlled trial among patientswho attended the smoking cessation clinic (SCC) at Fattouma Bourguiba University Hospital in Monastir, from June 2017 toFebruary 2020. Participants were assigned into two groups, acontrol arm receiving standard program and intervention armreceiving standard program and lung age announcement. The primary outcome was the smoking cessation rates after oneyear of follow-up between the intervention arm and the control arm.

**Results:** A total of 500 patients were recruited and randomized with 250 patients in each group. At one-year endpoint, a total of 456

patients were reachable for assessment, 236 in control group and 220 in spirometry group. This made the loss rate at 8.8% (54/500).

Six months cessation rate was 78 (33.1%) in control group and 106 (48.0%) in intervention group (p = 0.002).

The primary outcome smoking cessation rate after one year of recruitment was higher in the intervention group than the control group (25.5% versus 16.5%), with a considerable statistical significance (p = 0.019).

Moreover, spirometriclung age was significantly higher at paired comparison with chronologic age (58.81vs 46.54; p<.001); the mean differencewas 10.24 years but with considerable inter-individual variability.

**Conclusions:** Smoking cessation is still a challenging procedure with a high risk of relapse, making very valuable any approach that may increase motivation in both unmotivated and motivated smokers. This study is an additional evidence for spirometry and lung age announcement as motivators for smoking cessation.



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# FIGNL1 is a potential biomarker of cisplatin resistance in non-small cell lung cancer

### **Chenxu Meng**

Anhui Medical University, China

**Background and Objective:** Fidgetin-like 1 (FIGNL1) participates in tumor resistance by playing the function of homologous recombination repair(HRR). However, the role of FIGNL1 in non-small cell lung cancer (NSCLC) is still unclear. This study aims to understand the expression of FIGNL1 in NSCLC and preliminarily explore its relationship with cisplatin resistance.

Methods: FIGNL1 messenger RNA (mRNA) was analyzed in 1018 NSCLC tissues and 111 adjacent tissues using The Cancer Genome Atlas program.FIGNL1mRNA in cisplatin-resistant and cisplatin-sensitive cell lines was analyzed by the Gene Expression Omnibus project. FIGNL1 protein was detected in 58 NSCLC tissues and 58 adjacent tissues by immunohistochemistry. The relationship between FIGNL1, clinical pathological characteristics and disease-free survival was retrospectively analyzed. Gene ontology was used to analyze the biological process mainly involving FIGNL1, and STRING

online constructed its protein interaction network and screened the key genes (hub genes).

**Results:** The Cancer Genome Atlas showed that FIGNL1mRNA was higher in 1018 NSCLC tissues than in 111 adjacent tissues (P<0.05). In the dataset "GSE157692," FIGNL1mRNA was higher in cisplatin-resistant cell lines (P=3.80e-05). The hub genes in FIGNL1 and HRR directions are RAD51 and CCDC36. Immunohistochemistry showed that the FIGNL1 protein in 58 NSCLC tissues was higher than that in 58 adjacent tissues (P<0.01).FIGNL1 is associated with gender, histopathological type, and nerve invasion in NSCLC.The disease-free survival in NSCLC patients with high FIGNL1 expression was shorter (P=0.032).

**Conclusion:** FIGNL1 is associated with poor prognosis in NSCLC, and cisplatin resistance may be involved. These observations provide a clinical basis for exploring FIGNL1 as a potential biomarker for cisplatin resistance in NSCLC.



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Moringa oleifera
leaf meal
supplementation
modulate serum lipid
profile of rats fed
protein and mineral
deficient diets

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### Gloria Aderonke Otunola, Yanga N Mhlomi and Anthony Jide Afolayan

University of Fort Hare, South Africa

lobally, malnutrition is the greatest risk factor for illness and death, particularly amongpregnantwomenandyoungchildren. Protein deficiency causes severe and chronic infections, decreased nutrient absorption and direct nutrient losses. Micronutrients are central to cellular metabolism, maintenance, growth; support, prevent and cure various disorders in the course of life. Moringa leaves present a high content in micronutrients and macronutrients. Serum lipid profile of rats fed protein and micronutrients deficient diets supplemented with *Moringa oleifera* leaf meal (MOLM) was evaluated. Male Wistar rats (220g-290g) were randomly assigned into 5 groups of five animals

each, Group 1 was control; group 2 was protein-deficient diet without MOLM, groups 3, 4 and 5 protein-deficient diet supplemented with 3,5, 10 % MOLM. This was repeated for micronutrient-deficient rats. All animals were given feed and water ad libitum for 28 days. Serum lipid profile was measured using an automated chemistry analyzer. Protein deficiency led to significant (p<0.05) elevation of serum cholesterol and triglycerides in protein-deficient group compared to the control, which was slightly lowered with MOLM supplementation, but no significant difference (p<0.05) in HDL-C was observed in all the diets- (Table 1).

On the other hand, micronutrient deficiency



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Table.1. Quantitative analysis of polyphenolic TA extract by using HPLC.

	Р	rotein Deficient			
	Control	PD	PD3	PD5	PD10
Cholesterol	1.17±0.19a	2.43±0.51	1.93±0.19ab	2.13±0.15b	2.11±0.15b
Triglycerides	1.11±0.18a	3.26±0b	0.79±1.38a	3.22±0.21b	1.85±0.06a
HDL-C	1.03±0.14a	1.20±0.14ab	1.18±0.09a	1.13±0.12a	1.26±0.04ab
	Р	rotein Deficient			
	Control	MD	MD3	MD5	MD10
Cholesterol	1.17±0.19	0.98±0.07	1.10±0.03	0.99±0.11	0.69±0.11
Triglycerides	1.11±0.18	0.63±0.17	0.69±0.19	0.76±0.15	0.72±0.0
HDL-C	1.03±0.14	0.78±0.13	0.77±0.03	0.77±0.09	0.49±0.08

resulted in significant decrease in serum effect of protein and micronutrient deficiencies cholesterol, triglycerides and HDL-C compared to control (Table 1). This study revealed that MOLM supplementation mitigated the negative

on serum lipid profiles in rats.



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A structured group intervention (TüTASS) with focus on self-perception, mindfulness and social skills for children with autism spectrum disorder, ASD

Gottfried Maria Barth<sup>1</sup>, Drüsedau Laura<sup>1</sup>, Schoba Anja<sup>1</sup>, Götz Antonia<sup>1</sup>, Kleine Büning Lena<sup>1</sup>, Conzelmann Annette<sup>1,2</sup> and Renner Tobias<sup>1</sup>

<sup>1</sup>University Hospital of Tübingen, Germany <sup>2</sup>PFH – Private University of Applied Sciences, Germany

**Objectives**: Autism spectrum disorders (ASD) represent a set of long-lasting severe neurodevelopmental conditions and effective therapeutic interventions are needed. Recent research points to the importance of including mindfulness-based elements to improve emotion and body perception in the psychotherapy of patients with ASD. Therefore, we developed a structured group psychotherapy program The Tübinger Training for Autism Spectrum Disorders (TüTASS) which focuses on mindfulness-based training elements.

**Scope:** In several steps we developed a group-intervention for 5-6 children in each group and applied it to 52 children with diagnosis autism spectrum disorder. A pilot study of the Tübingen Group Training for Autism Spectrum Disorders (TüTASS) has demonstrated that mindfulness-based elements achieve additional positive effects. To build on these findings, the TüTASS training was adapted and expanded.

Methods used: The TüTASS includes 20 90-minute appointments starting with the basic skills of emotions, body, and communication, which are then transferred to personal, family, peer, and school spheres. The appointments have a fixed, consistent structure and each includes a body awareness exercise. The psychometric assessment comprised five standardized questionnaires/ scales evaluating on the basis of parents and patients self-reports the child's social responsiveness, behavior, strengths and difficulties, quality of life, and depressive symptoms before and after training completion.

**Results:** The results showed improvements in pre-post comparison in behaviours associated with autism, as well as in externalising and internalising behaviours as assessed by parent reports, participant self-reports, and independent raters in participating children. Furthermore, the perceived parent burden in



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relation to their children decreased, whereas the participants self-rated quality of life increased. Overall, both the participants and their parents rated the TüTASS very positively in rating sheets and in free feedback.

**Conclusion:** This training program was developed to bridge the gap of lacking

mindfulness-based interventions with the aim to optimize the course of ASD, especially with respect to behavioral disturbances and social-emotional problems. Therefore, TÜTASS training could well be a useful treatment tool for groups of patients with ASD.



## Advances in Clinical Research and Trials

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Evaluation
of bacterial
composition
and viability of
equine feces after
processing for
transplantation

### Julia Heinen, Clemence Loublier, Bernard Taminiau, Laureline Lecoq, Helene Amory, George Daube and Carla Cesarini

University of Liège, Belgium

lecal microbiota transplantation (FMT) has been used empirically for decades in equine medicine to treat intestinal dysbiosis but evidence-based information is scarce. This in vitro study aimed at assessing the effect of a commonly used pre-FMT processing method on the bacterial composition and viability of the fecal filtrate. Three samples of fresh equine manure (T0) were processed identically: the initial manure was mixed with 1 L of lukewarm water and chopped using an immersion blender to obtain a mixture (T1), which was left uncovered during 30 min (T2) and percolated through a sieve to obtain a fecal filtrate (T3). Samples were taken throughout the procedure (Tn) and immediately stored at 4°C until processing. The 16S rDNA amplicon

profiling associated with propidium monoazide treatment was performed on each sample to select live bacteria. Analyses of a and β diversity and main bacterial populations and quantitative (qPCR) analysis were performed and statistically compared (significance p < 0.05) between time points (T0- T3). No significant differences in ecological indices or mean estimated total living bacteria were found in the final fecal filtrate (T3) in regard to the original manure (T0); however, relative abundances of some minor genera (Fibrobacter, WCHB1-41\_ge and Akkermansia) were significantly different in the final filtrate. In conclusion, the results support the viability of the major bacterial populations in equine feces when using the described pre-FMT protocol.



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The moderating role of family resilience in the relationship of bullying victimization, adverse childhood experiences, and poverty status to adolescents internalizing disorders



### Jungtae Choi

Sungkyunkwan University, South Korea

**Objectives:** The present study aimed to explore whether family resilience would moderate the effects of bullying victimization, Adverse Childhood Experiences (ACEs), and poverty status on adolescent internalizing disorders.

Methods: This study used the 2016 National Survey of Children's Health (NSCH)and included 20,708 adolescents aged 12 to 17 years (M = 14.7,SD = 1.70). Internalizing disorders indicated adolescents depression and anxiety problems and were measured by summing two items (scoring from 0 to 2) (a =.72). Bullying victimization was measured with one item(0=no, 1=yes). Adverse childhood experiences (ACEs) were measured with nine questions (income hardship, divorce, death, jail, domestic violence, neighborhood violence, mental illness, drug use, and discrimination) (0=no, 1=yes). This study summed theitems ranging from 0 to 9. Higher scores indicated more exposure to ACE.Poverty status was measured with the federal poverty level (FPL), which isan economic measure that decided whether the income level of families wasbelow the poverty line (Branum et al., 2012). Family resilience was measured by four items (scoring from 0 to 3). This study calculated the sum of the items ranging from 0 to 12. Thus, higherscores indicated higher family resilience ( $\alpha = .89$ ).

For statistical analysis, hierarchical multiple regression was conducted toexamine the relationship of bullying victimization, ACEs, and poverty status with adolescents internalizing disorders and explore the moderating role of family resilience on that relationship.

**Findings:** The study found positive associations of bullying victimization, ACEs, and poverty status with adolescents internalizing disorders. Family resilience moderated the effects of bullying victimization and ACEs on adolescents internalizing disorders.

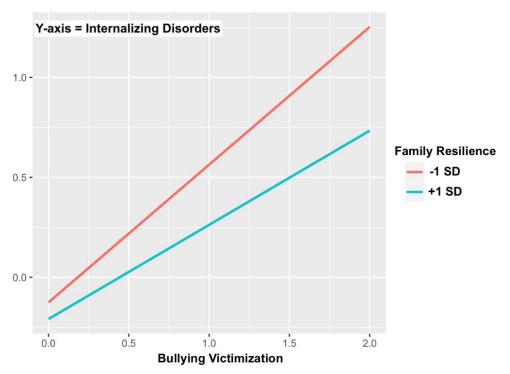
**Conclusion:** The findings suggest that to prevent adolescents internalizing disorders, it is critical to promote family resilience and reducebullying victimization, ACEs, and poverty.



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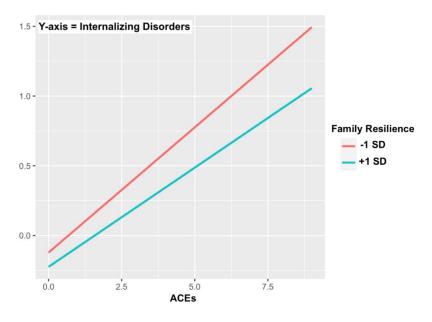
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**Figure 1.** Family resilience as a moderator of the association between bullying victimization and internalizing disorders



Note. SD = standard deviation

**Figure 2.** Family resilience as a moderator of the association between ACEs and internalizing disorder



Note. SD = standard deviation



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# Correlation between sociodemographic factors and tooth loss in adolescents in Belgrade, Serbia



### Maja Pavlovic and Veljko Kolak

University Business Academy Novi Sad, Serbia

**Introduction:** Dental caries and orthodontic treatments are the most common reasons for tooth extraction among younger population. Socio-demographic, cultural and behavioural factors affect both tooth loss and reasons for extraction in adolescent period of life.

**Objective:** This study was to assess the prevalence of tooth loss, reasons for extraction and factors that can influence reasons for tooth extraction in examined population in urban area.

**Method:** Epidemiological cross-sectional study included 273 randomly selected, first and second grade high school students, in Belgrade in the period of May-June 2022. The research instruments were questionnaire and clinical examination. The questionnaire was divided in 9 parts focusing on socio-demographic characteristics, habits, attitudes and behaviour related to general and oral health. Clinical examination was used to gather data about tooth loss and dental status. Statistical analysis was performed using the software package SPSS Statistics.

Results: Most participants identified caries

complications as the indication for tooth extraction (82.8%). Almost one fifth of participants (21% girls and 16,3% boys respectively) have extracted at least one tooth. Data analyses showed existence of connection between extracted teeth and sociodemographic factors. Investigation of nature of connection between dependent variable -reason for tooth extraction and independent variables pointed out on significant influence socio-demographic characteristics participants as well as theirs oral health habits (p<0,001). Those two independent variables had positive influence on reason for extraction meaning that adolescents with higher scores had extracted teeth due to planned orthodontic therapy.

**Conclusions:** The loss of permanent teeth in adolescent age is a problem that may influence all aspects of life, because it affects aesthetic appearance, self-confidence and the entire quality of life and not just masticatory dysfunction. Socio-demographic conditions, such as parents employment, family income and financial status significantly influenced the number of participants with extracted teeth.



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# The status of clinical research coordinators in Israel sites

#### Michal De-Wolf and Ornit Cohen

Wolfson Medical Center, Israel

**Background:** At Israeli medical organizations, clinical trial coordinators (CRCs) are essential to the accomplishment of clinical research. On the other hand, little is known regarding the state of CRCs in the Israeli clinical trial sector.

**Methods:** To understand the current state of CRCs in this field, an online survey was conducted among a Facebook group of approximately 5,000 employees working in clinical trials in March 2022. The survey was designed to gather information about the demographics, work experiences, and job satisfaction of CRCs in Israel. The survey included questions about the participants job duties, training and education, and overall satisfaction with their jobs. In addition, the survey included questions about the challenges faced by CRCs in their work and their perceptions of the support and resources available to them.

**Results:** 61 people—mostly women (95%)—representing 17 medical centers in Israel answered, with ages ranging from 24 to 60

and work histories varying from 0 to 20 years. With a median income of 10,000 NIS after four years of employment, a substantial positive link between work experience and pay was also discovered.

**Discussion:** Finding suggests that there is a lack of uniform training for CRCs in Israel, which may have an impact on the effectiveness and quality of clinical trials. In addition, CRCs tend to earn more the more experience they have, which is consistent with patterns in other industries.

**Conclusion:** To ensure CRCs are fairly compensated for their significant contributions to the profession, efforts should also be taken to eliminate compensation inequities based on the job experience. Additional investigation and analysis into the function and experiences of CRCs in Israel may yield insightful findings and contribute to enhancing clinical trials overall efficacy in the nation.



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Assessment of binary agarose-carbopol buccal gels for mucoadhesive drug delivery: Ex vivo and in vivo characterization

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<sup>4</sup>Government College University Faisalabad, Pakistan

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<sup>7</sup>University of Jeddah, Saudi Arabia

8University of the Punjab, Pakistan

<sup>9</sup>University of Education, Pakistan

garose (AG) is a naturally occurring biocompatible marine seaweed extract that is converted to hydrocolloid gel in hot water with notable gel strength. Currently, its mucoadhesion properties have not been fully explored. Therefore, the main aim of this study was to evaluate the mucoadhesive potential of AG binary dispersions in combination with Carbopol 934P (CP) as mucoadhesive gel preparations. The gels fabricated via homogenization were evaluated for ex vivo mucoadhesion, swelling index (SI), dissolution and stability studies. The mucoadhesive properties of AG were concentration dependent and it was improved by the addition of CP. Maximum mucoadhesive strength (MS) (27.03

g), mucoadhesive flow time (FT) (192.2 min), mucoadhesive time in volunteers (MT) (203.2 min) and SI (23.6% at 4 h) were observed with formulation F9. The mucoadhesive time investigated in volunteers (MT) was influenced by AG concentration and was greater than corresponding FT values. **Formulations** containing 0.3%, w/v AG (F3 and F9) were able to sustain the release (~99%) for both drugs till 3 h. The optimized formulation (F9) did not evoke any inflammation, irritation or pain in the buccal cavity of healthy volunteers and was stable up to 6 months. Therefore, AG could be considered a natural and potential polymer with profound mucoadhesive properties to deliver drugs through the mucosal route.



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## Is Ivermectin effective in treating COVID-19?

#### Ning Hou<sup>1</sup>, Shuangshuang Yang<sup>1,2</sup> and Shan Shen<sup>1</sup>

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oronavirus disease 2019 was first discovered in December 2019 and subsequently became a global pandemic with serious political, economic, and social implications worldwide. We urgently need to find drugs that can be effective against COVID-19. Among the many observational studies, ivermectin has attracted the attention of many countries. Ivermectin is a broadspectrum antiparasitic drug that also has some antiviral effects. We reviewed studies related to ivermectin for the treatment of COVID-19 over the last 2 years (2019.12–2022.03) via search engines such as PubMed, Web of Science, and EBSCOhost. A total of 168 publications were screened, and 18 studies met the inclusion criteria (n = 3,248). Seven studies showed a lower mortality rate in the ivermectin group than in the control group, six studies found

that the ivermectin group had a significantly fewer length of hospitalization than the control group, and eight studies showed better negative RT-PCR responses in the IVM group than in the control group, but these studies are not powered sufficiently to detect differences in the secondary outcomes, so a positive conclusion could not be reached. Our systematic review indicated that ivermectin may be effective for treating mildly to moderately ill patients, but the result is still in the early stages of clinical application as an antiviral drug and whether it has definite efficacy against COVID-19 needs to be supported by more controlled clinical studies with large samples. Therefore, selfmedication is not recommended for COVID-19 patients. Clinicians must take IVM with caution based high-level evidence and benefit-risk assessment results.



## Advances in Clinical Research and Trials

March 21, 2023



# Information system with databases for studies of substances - potential medical preparations for hypoxia disorders treatment

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ypoxia is widely spread phenomenon; it can be caused by hemorrhage, aviation accidents, technogenic environmental pollution influence, intoxication, diseases, and other reasons. Discoveries of new potential medical preparations for pharmacological treatment of these disorders are really important. Objectives of our work were studies of different substances - potential medical preparations for pharmacological corrections of hypoxic disorders, with parallel development of information system with databases for ordering information about these substances, other information necessary for researcherexperimenter. For these works a wide spectrum of standard biochemical methods were used for pharmacological agents testing on Wistar rats in laboratory conditions; information system development using a set of information computer technologies, databases construction in parallel was done. During some years we studied some such substances: non-protein factor of spleen- splenozide, derivatives of succinic acid- yackton, sufan. According to our experiments all studied substances could correct pathological changes in energy metabolism,

the first three substances prevented reduction of anti-oxidant cell potential, caused decrease of lipid peroxidation processes. During nitrite intoxication splenozide and yackton caused visible antioxidant effects, optimization of pathologically changed metabolic processes. Later C60 fullerene possible role in hypoxia states correction was investigated as well.

Obtained data, other relative laboratory information were recorded in developed computerized working place for researcher with databases, friendly interface, "Personal mini library", links with electronic libraries in Internet; necessary services were developed. For hospital such IS should be supplemented by automated work place for medical staff, developed by Dr.Aralova N.I. In conclusion, in the result of the work done the information system with databases and automated work places for researchers and medical staff were suggested, it permitted to study hypoxia effects and their correction by novel pharmacological agents in laboratory and hospital conditions.



## Advances in Clinical Research and Trials

March 21, 2023



Rare and emerging micro-organisms causing infection in tertiary care centerin background of COVID-19 pandemic



#### Rahul VM and Snehali

Narayana Hrudayalaya Institute of Allied Health Sciences, India

**Background:** The number of infectious diseases that are emerging or re-emerging (EIDs) on a global scale is growing. The COVID-19 pandemic was one such disease. Beyond viruses, other microorganisms are also causing of EIDS, especially bacterial species. In a tertiary care facility, bacterial infections need to be closely monitored and tackled. Sudden outbreaks of infections not only add to the disease burden but also lead to a substantial financial burden for both the patient and the hospital.

**Data Collection:** All patients who visited NH Health City between January 2017 and December 2021 and microbiological evaluation were identified from EMR at a tertiary referral center. All relevant demographic and clinical data were collected. Data on disease outcome (defined as complete recovery from infection and death), ICU admission, ventilation, medication, immunosuppression, interventions, and comorbidities were recorded. The response was assessed clinically and supported by microbiology culture reports. The data were analyzed and statistical analysis was carried out using the IBM® SPSS® Statistics software package Version: 28.0.0.0.

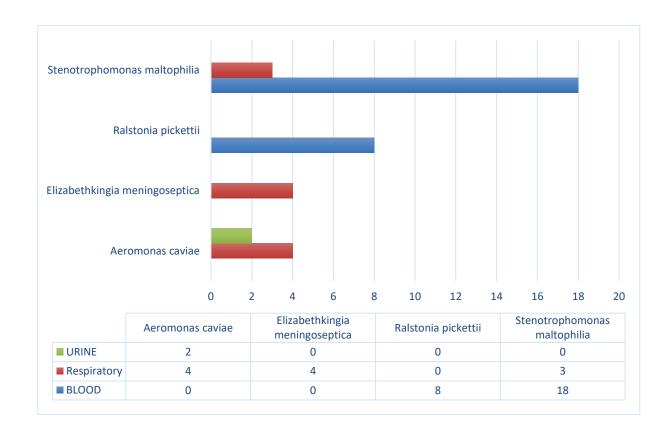
Results: During the study period, microbiology lab received a total of 49,992 clinical samples for microbial identification and AST. Out of which 214 (0.42%) patients grew microorganisms (M=129; 60.3; median age 59 years). Using MALDI-TOF technology we were able to identify 39(18.2%) rare and emerging bacteria. In the study population, the most frequently isolated bacterial species causing Stenotrophomonas was maltophila (9.8%, n= 21), followed by Ralstoniapickettii (3.7%,n=8),Aeromonas caviae(2.8%, n=6), and Elizabethiameganoseptica (1.8 %, n=4). Among the 39 patients growing rare emerging microorganisms, 12.8% (n=5) had active COVID-19 infection during the period of data collection. The multivariate analysis of factors like SAR-CoV2 co-infection, presence of comorbidities, iatrogenic, and interventions, did not have any statistical significance to mortality, 28 days post-diagnosis.

**Conclusion:** The early, accurate diagnosis of invasive EIDs is important in the effective management that can improve clinical care and substantially reduce morbidity and mortality. Studies like ours are the building blocks for robust antimicrobial stewardship programs in any tertiary care setting.



## Advances in Clinical Research and Trials

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**Figure 1:** Graphical representation of proportional clinical samples growing rare and emerging microorganisms



#### **Advances in Clinical Research and Trials**

March 21, 2023



**Extranodal MALT** lymphoma in the oral cavity- A series of three cases with review of literature



#### Ramandeep Kaur, Tanuja Shet, Dhanlaxmi Shetty, Bhausaheb P Bagal, Sumeet Gujral and Manju Sengar

Tata Memorial Hospital, India

**Background:** Diagnosis of MALT (mucosa associated lymphoid tissue) lymphoma in the oral cavity is challenging. There is a great overlap in the histopathologic, immuno-histochemical and molecular features of MALT lymphoma with reactive lymphoid proliferations. The literature shows a very few case reports of primary MALT lymphoma of oral cavity.

Methods: We discuss the histopathologic, immuno-histochemical, cytogenetic features, treatment, and behaviour of 3 cases of primary MALT lymphoma oral cavity along with review of literature.

**Results:** The age ranged from 40 to 57 years (male to female ratio = 2:1). The sites involved were hard palate, bilateral gingivobuccal sulcus, and right buccal mucosa. The most common histology was centrocyte-like (2 cases). Lymphoepithelial lesions were absent.

On immunohistochemistry, all tumours showed diffuse strong CD20 and bcl2 expression with strong and diffuse MNDA staining in one case. IgH; MALT1 translocation was not seen in any of these cases. One patient received local radiotherapy, one received steroids; while the case 3 received R-CHOP (Rituximab, cyclophosphamide, hydroxydaunorubicin hydrochloride, vincristine, and prednisone) chemotherapy. Two patients had complete remission while one had recurrence.

**Conclusion:** MALT lymphoma of oral cavity shows a wide spectrum of morphology with presence of transformed cells, that may lead to misdiagnosis of diffuse large B cell lymphoma. The treatment guidelines are not well established but a tendency to excise MALT lymphomas of oral cavity has been observed. Nevertheless, MALT lymphoma of oral cavity appears to be an indolent disease.



## Advances in Clinical Research and Trials

March 21, 2023



## DSUR Process: The SPEED concept

#### R Thorat and U Bhanushali

SIRO Clinpharm Pvt. Ltd., India

he Development Safety Update Report (DSUR) is a structured document intended to submit to the health authorities for the drugs under developmentannually. The DSUR include the comprehensive and thoughtful information based on the annual review and evaluation of the safety information collected during the reporting period from the drug developmental program irrespective whether or not it is marketed.

Since the DSUR include an annual review of the information, huge flow of the information can be expected from the different stakeholders for the particular DSUR which should be analyzed, process and finalized within the stipulated

timeline. In order to overcome this challenge we developed a SPEED concept in house for the effectively managing the time and preparation of the DSUR with higher accuracy. This concept utilizes,

- 1. Day -90 approach
- 2. Effective resource and workload management
- 3. The DSUR coordinators

Following this concept, we achieved a significant improvement in the DSUR process and achieve improved overall DSUR quality under stringent timelines.



## Advances in Clinical Research and Trials

March 21, 2023



A comparative study of purified lactoferrin from camel milk loaded on Polyfluorooctyl bromide and calcium alginate nanoparticles, and its effect on growth of osteoblasts Cell Line MG-63

### Saeid Zibaee<sup>1</sup>, Jamshidkhan Chamani<sup>2</sup>, Noosha Zia-Jahromi<sup>3</sup>, Jamshidkhan Chamani<sup>2</sup> and Noosha Zia-Jahromi<sup>2</sup>

<sup>1</sup>Agricultural Research, Education and Extension Organization (AREEO), Iran <sup>2</sup>Islamic Azad University, Iran

**Background:** Osteoporosis is a common disease characterized by low bone mass that can harm health. Lactoferrin has antimicrobial and plays a role in iron absorption, increase Osteogenesis and increase the immune responses. One of the goals of nanotechnology is mounting the drug on nanoparticle carriers and send them into the target cells.

Materials and methods: In this study, lactoferrin (LF) of Camel milk were isolated using ion exchange chromatography and the purity and molecular weight was confirmed by SDS-PAGE electrophoresis and TBM test. The extracted LF has been purified by the application of HPLC and SDS-PAGE techniques.

The concentrations of 25 and 100  $\mu g/mL$  of LF were uploaded on perflourooctylbromide

-NEPs(PFOB-NEPs). The interactions between LF and PFOB, LF and Alg have been studied by multiple spectroscopic as well as the zeta potential, and DLS particle size distribution. Results have displayed the quenched emissions of LF upon their interactions with PFOB and Alg.The effects of LF and LF were uploaded on PFOB-NEPs and Alg on growth of osteoblasts Cell Line (MG-63) was studied using MTT assay.

**Results:** The average particle size before and after LF loading on PFOB did not change. Also, the zeta potential of nanoparticles is from -18.43 (without LF) has changed to +21.61 (LF 100  $\mu$ g/ml), which confirms the loading of LF into PFOB-NEPs.The zeta potential value of LF has faced a decrease through the formation of LF– Alg complex. The best loading in both concentrations has occurred at the pH = 8.



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The results were shown, LF and LF were uploaded on PFOB-NEPs and Alg-NEPs increase Osteoblast cells proliferation significantly and There aren't a significant difference between LF and LF were uploaded on PFOB- NEPs and there are a significant

difference between LF and LF were uploaded on Alg-NEPs in both concentrations. The increase Osteoblast cells proliferation under the influence of different concentrations of LF uploaded on PFOB and Alg significant differences were shown.



## Advances in Clinical Research and Trials

March 21, 2023



# A comparison of endovascular aneurysm repair and open repair for ruptured aortic abdominal aneurysms



#### Samaher A.Alnefaie, Yasser A.Azahrani and Bashair S.Alzahrani

King Fahd Military Hospital, Saudi Arabia

**Background:** Management modalities of ruptured Abdominal aortic aneurism (AAA) include ruptured open aneurysm repair (rOAR) and ruptured endovascular aneurysm repair (rEVAR). In this study, we aim to systematically review all the previously published randomized controlled trials (RCTs) that compared rOAR and rEVAR..

**Methods:** A systematic search was performed in the following databases: PubMed, Scopus, Web of Science, Google Scholar, Clinical trials, and others with all the potentially relevant keywords that were adjusted to meet the search strategy for each database to collect all the relevant studies that were published up to January 2021.

**Results:** A total of 11 studies were identified through our comprehensive search. Among these studies, seven represented the

IMPROVE trial, two represented the AJAX trial, two represented the Nottingham and ECAR trials, each, while the remaining four studies were not RCTs, however, these were included in the discussion as they obtained data from the IMPROVE trial. The IMPROVE trials preferred EVAR use due to the potential survival benefit and improved quality of life, although the EVAR and OAR had similar mortality rates. In the AJAX and ECAR, the mortality rates favored EVAR over OAR with no significance while the opposite was noticed in the Nottingham trial with no significance also. Similar rates of re- interventions and complications were also noticed and some studies reported that EVAR is cost-effective.

**Conclusion:** No consensus has been found to favour one of the modalities over the other. However, trials seem to favour EVAR on a short-term basis, while OAR is superior regarding the long-term outcomes.



## Advances in Clinical Research and Trials

March 21, 2023



Alpha lipoic acid potentiates the myocardial function and anti arrhythmic effects of ischemic post conditioning in the setting of cardiac ischemia/reperfusion injury in diabetic rats

#### Sanaz Gholami, Reza Badalzadeh and Alireza Alihemmati

Tabriz University of Medical Sciences, Iran

**Background:** Prevention of lethal ventricular arrhythmias induced by myocardial ischemia/reperfusion (I/R) in diabetic patients is the major goal of cardio-protective strategies. Here, we aimed to examine the anti-arrhythmic effect of ischemic postconditioning (IPostC) and alpha-lipoic acid (ALA) in myocardial I/R injury of type-II diabetic rats, focusing on the involvement of connexin-43 and nitric oxide (NO) in this context.

**Methods:** Diabetes (duration of 12 weeks) was induced by high-fat diet and low dose of streptozotocin in thirty male Wistar rats (12 weeks old, 200-250 g). After mounting the hearts on the Langendorf apparatus, I/R was induced by the ligation of left anterior descending coronary artery for 35 min, and reperfusion for 60 min. ALA (100 mg/kg/day) was administered orally in diabetic rats for five weeks before I/R. IPostC was applied immediately at early reperfusion. The arrhythmias were evaluated according to the Lambeth convention. Connexin-43 expression

and NO levels were assessed by western blotting and Griess calorimetric method.

Results: IPostC could not significantly decrease the number, duration, premature incidence of ventricular ventricular contraction, tachycardia, ventricular fibrillation, also severity of arrhythmias in diabetic hearts. However, IPostC in combination with ALApreconditioning significantly decreased the above mentioned parameters and recovered cardiac function compared with untreated or monotherapies-received diabetic rats (p< 0.05 to P<0.001). Furthermore, this combination therapy significantly increased connexin-43 expression and NO levels, compared with untreated diabetic rats (P<0.01).

**Conclusion:** Preconditioning with ALA restored cardio-protection and antiarrhythmic effect of IPostC in diabetic hearts. Increased connexin-43 expression and NO levels may be the key players in this cardio-protection.



## Advances in Clinical Research and Trials

March 21, 2023



A systematic review on latest approaches of automated sleep staging system using machine intelligence techniques

#### Santosh Kumar Satapathy<sup>1</sup> and Hari Kishan Kondaveeti<sup>2</sup>

<sup>1</sup>Pandit Deendayal Energy University, India <sup>2</sup>VIT-AP University, India

Background and **Objective:** Sleep staging plays a vital role in sleep research because sometimes sleep recordina errors mav cause severe problems like misinterpretations of the changes in characteristics of the sleep stages, medication errors, and finally, errors in the diagnosis process. Because of these errors in recordings and analysis, the sleep behavior and automated sleep staging system are adopted by different researchers with different methodologies. This study identifies specific challenges with the existing studies and highlights certain points that support the improvement automated sleep staging-based polysomnography signals.

**Methods:** This work provides a comprehensive review of an automated sleep staging system, which was contributed by the different researchers in

the recent research developments using Electroencephalogram, Electrocardiogram, Electromyogram, and combinations of these signals

**Results:** Our review in this research area shows that single-model and multimodal signals are used for sleep staging, and also we have observed some great points from the existing methodologies: (1) It has been noticed that 30-s length of the epoch of EEG signals may not be sufficient to extract enough information for discriminating the sleep patterns but in the other hand that a 10-s and 15-s length epoch is well suitable for sleep staging, (2) due to similar characteristics on N1 and REM sleep stages, most of traditional classification the models misclassified N1 sleep stages as REM stage, which alternatively degrades the sleep stagging performance,(3) consideration of



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heterogeneous form signal fusions can give the improvement results on sleep staging, and (4) applying deep-learning based models like convolutional neural network (CNN) and extended short-term memory network (LSTM), deep models, combinedly to significant PSG signals can lead to more robust automatic sleep staging results.

**Conclusions:** The review mentioned above

points simultaneously improves automated sleep staging by polysomnography signals. These points can help to focus our research work from the traditional feature extraction method to systematic improvements such as automatic feature recognition without explicit features, a proper characterization of the sleep stage's behavior, safety, and reduced cost.



## Advances in Clinical Research and Trials

March 21, 2023



## Cannabis recent use in sudden unexpected deaths

#### Teresa Huertas, Teresa Soriano, David Olano and Manuel Salguero

National Institute of Toxicology and Forensic Sciences, Spain

**Objective:** The objective was to review all sudden unexpected death received in our laboratory for the four years period (2018 – 2021) after a recent cannabis use. Parameters evaluated were age, antecedents, sex, cause of death and toxicological results

**Scope:** To elucidate whether cannabis use increase the risk to suffered from sudden death

**Methods:** The study was carried out by searching the LIMS database of the Department of Seville from INT-CF from 2018 until 2021, for all cases of sudden unexpected deaths related to cannabis use. We selected those in which cannabis use was recent due to the presence of THC in blood postmortem.

Blood samples were screened for cannabis by CEDIA and tetrahydrocannabinol (THC), 11-hydroxy-Δ9-tetrahydrocannabinol (11-OH-THC) 11-nor-Δ9-tetrahydrocannabinol-9carboxylicacid (THC-COOH) were confirmed and quantified using solid-phase extraction (SPE) followed by gas chromatography tandem mass spectrometry (GC-MS/MS). The cut-offs applied were 1 ng/mL for THC and 11-OH-THC and 5 ng/mL for THC-COOH.

**Results:** 48 sudden unexpected deaths following recent cannabis use were recorded.

	Sudden unexpected deaths	Sudden unexpected deaths related to cannabis use	Sudden unexpected deaths after recent cannabis use
TOTAL	7150	262	48

**Table 1.** Sudden unexpected death number

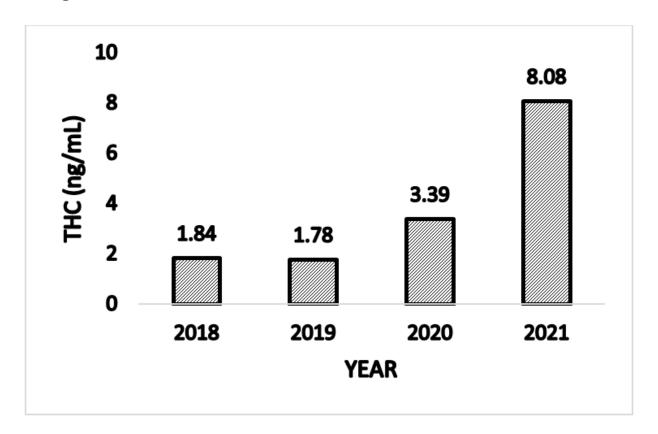


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In 87.5% of cases were male, the age decedent had pathological antecedents rangeof 16 to 74- years-old, being the like arterial hypertension, obesity, epilepsy. median 50-years-old and the mode 47-years-old. In 77% of cases the cause of death was cardiogenic, 6.2% subarachnoid hemorrhage and the rest other causes. Most

concentrations detected postmortem have been increasing for the period studied (Figure 1).



**Figure 1.** THC concentrations in blood postmortem

The number of deaths increased from 7 in 2018 until 21 in 2021.

Conclusion In people with certain pathologies and/or alcohol and tobacco use habits, cannabis use is a risk factor that could contribute to sudden unexpected death.



## Advances in Clinical Research and Trials

March 21, 2023



Impact of FDI, technological innovation and digital technology on CO<sub>2</sub> emissions and profits of high-tech industries: Evidence from data of China



#### Wang Zhaocheng

School of economics of Sichuan University, China

riven by the global green technology and high technology, digital technology and green high technology have brought effects on the environment. Under this background, what impact does the green production brought by the adoption of high technology and digital technology have on the economic subject? Is it beneficial to the environment, economy, society, or not. Specifically, when adopting digital technology and high-tech technology, which indicators and technical systems have the ultimate effect on the economy, the environment, the main body of the company, and social welfare. Through empirical research, it has proved the role of digital technology and green high-tech technology in the economy. It also explains the positive effects of important elements on the environment and economy.

This study measures the impact of FDI

and technological innovation from 28 provinces in China on the carbon emissions of high-tech industries. The study used provincial data of China from 2000 to 2018. In addition to checking unit root characteristics, structural fracture and cointegration, this study also uses quantile regression to estimate the long-term relationship between research variables. The research results reveal the negative impact of foreign direct investment on carbon emissions. Technological innovation has a positive impact in the first three quantiles, and a negative impact in the next six quantiles. These results show that foreign direct investment and technological innovation shape the energy intensity of high-tech industries, which leads to the fluctuation of carbon emissions over time. After controlling the impact of urbanization, energy intensity and economic growth, this study suggests that policy makers should



## Advances in Clinical Research and Trials

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emphasize the heterogeneity of FDI and technology lead emissions in different quantiles in the process of CO<sub>2</sub> emission reduction. At the same time, all A-share listed companies in 2007-2021 are used as the initial research sample. From the regression results of the two-way fixed effect model of fixed industries and years, it can be seen that the core explanatory

variable of this paper, digit, will have a positive impact on salary, and this impact is significant at the level of 5%, that is, under the same conditions, the higher the degree of digitalization of enterprises, This will lead to an increase in the proportion of employee compensation in the total net profit of the enterprise.



## Advances in Clinical Research and Trials

March 21, 2023



Comparison of the
Effectiveness of Endometrial
Receptivity Analysis (ERA)
to guide personalized
embryo transfer with
conventional frozen embryo
transfer in 281 chinese
women with recurrent
implantation failure

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<sup>2</sup>Chengdu Jinxin Research Institute of Reproductive Medicine and Genetics, China

**Background:** This study aimed to compare the effectiveness of endometrial receptivity analysis (ERA)-guided personalized embryo transfer (pET) with conventional frozen embryo transfer (FET) in 281 Chinese women with recurrent implantation failure (RIF).

**Material/Methods:** A total of 281 eligible patients with RIF were recruited and assigned to ERA (ERA followed by pET) and FET groups. The clinical pregnancy outcomes were compared between the 2 groups.

**Results:** There were no significant differences between the ERA and FET groups in terms of endometrial thickness on the day of embryo transfer, mean attempts of assisted reproductive technology (ART) treatment, anti-Mullerian hormone,

follicle-stimulating hormone, or antral follicle count in the fresh cycle (P>0.05). The ERA test identified 35% of samples as receptive and 65% as nonreceptive, and comparable pregnancy outcomes were observed between receptive and nonreceptive patients (P>0.05). Higher pregnancy and implantation rates were found in the ERA group than in the FET group (P<0.01), while no significant differences were detected between the 2 groups in terms of miscarriage rates (P>0.05).

**Conclusions:** In this study of Chinese women with RIF undergoing in vitro fertilization and embryo transfer, ERAguided pET resulted in a significant improvement in pregnancy and implantation rates when compared with FET.



#### About us

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