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April 15-16, 2019 | Milan, Italy

CELL AND GENE THERAPY 2019 & PUBLIC HEALTH CONGRESS 2019



SCIENTIFIC TRACKS & ABSTRACTS

DAY 1

DAY 1 SESSIONS
APRIL 15, 2019

Advanced Gene Therapeutics | Public Health and Epidemiology | Nutrition and Health Nutraceuticals and Health Welfares | Stem Cell Therapies

SESSION CHAIR

Bryan Poltilove
Thermo Fisher Scientfic, USA

SESSION INTRODUCTION

Title: Using wave and energy theories on fine-tuning food and exercise to control ppg (math-physical medicine)

Gerald C Hsu, EclaireMD Foundation, USA

Title: Develop of guidelines for collective catering public procurement integrated with sustainable development goals

Giulio Barocco, University of Trieste, Italy

Title: HEK293-derived Adeno Associated Virus (AAV) purification: Comparison of small-scale laboratory production towards industrial format using monoliths

Ales Strancar, BIA Separations, Slovenia

Title: Molecular mechanisms in support of allogenic placenta-derived stem cell transplantation without immunosuppression

Gramignoli R, Karolinska Institutet, Sweden

Title: Thinking inside the box: Centralized vs decentralized manufacturing

Vered Caplan, Orgenesis Inc., Israel

Title: Quality of life for children with cystic fibrosis in gaza strip

Yaser M Hamdouna, University of Palestine, Palestine

Title: Functional disorders, vascular risks and, malignant diseases. Prevention by subjective lowering of preprandial blood glucose (by planning and recognizing initial hunger)

Mario Ciampolini, University of Florence, Italy

Title: Proposal of a reference pattern for nutritional evaluation in nurseries Chillán, 2012

Alejandra Melendez Gonzalez, University of the Americas, Chile

Gerald C Hsu, Arch Gen Intern Med 2019, Volume 3 | DOI: 10.4066/2591-7951-C2-026

USING WAVE AND ENERGY THEORIES ON FINE-TUNING FOOD AND EXERCISE TO CONTROL PPG (MATH-PHYSICAL MEDICINE)

Gerald C Hsu
EclaireMD Foundation, USA

Introduction: The author conduct big data analytics of food exercise and derived practical tips for controlling postprandial plasma glucose wave.

Methods: He used both optical physics and signal processing techniques to develop PPG prediction model. He realized weight is merely a physical representation of internal energy exchange in human body. The energy infusion comes mainly from food, whereas energy diffusion mainly via exercise and activities. We should avoid having energy imbalance (disequilibrium); otherwise, the excessive (left-over) energy will damage our internal organs. In addition to his collected ~1.5M metabolism data and ~8M food/meal data, he further collected additional 14,400 glucose data during 174 days (5/5/2018-10/25/2018 with 80 measurements / day). He observed and analyzed these glucose waveforms and phenomena in detail using wave and energy theories from physics and engineering and also calculated their associated energy levels. Finally, he identified some practical ways to either avoid the building-up of ultrahigh amplitude of glucose wave or wearing off its cumulative energy quickly.

Results: He developed a few computational formulas and practical tips as stated below to "fine-tune" both energy infusions by food and energy diffusion through exercise in order to "wear-off" the excessive energy generated by glucose. He also identified a reasonable energy perturbation range (-7% to +17%); Predict PPG level before eating meal; don't eat >30 grams of carbs/sugar each meal. It can push PPG peak above 160 mg/dL; walk minimum 1500 steps after each meal, 4,000 steps for severe diabetes patients. More rigorous exercise can bring down PPG peak value, but stretch walking period can wear off energy to make glucose waveform look like a "Grand Canyon" shape which still has a high amplitude but contains much less energy; don't eat snacks too close to next meal to avoid building a glucose waveform similar to "Himalaya Mountain" shape which indicates massive energy.

Conclusion: His method and practical tips can "fine-tune" the energy infusion caused by food and energy diffusion (post-meal walking) and provide guidance to T2D patients for achieving a better PPG control.

BIOGRAPHY

Gerald C Hsu received an honorable PhD in Mathematics and majored in Engineering at MIT. He attended different universities over 17 years and studied seven academic disciplines. He has spent 20,000 hours in T2D research. First, he studied six metabolic diseases and food nutrition during 2010-2013, then conducted research during 2014-2018. His approach is "math-physics and quantitative medicine" based on mathematics, physics, engineering modelling, signal processing, computer science, big data analytics, statistics, machine learning and AI. His main focus is on preventive medicine using prediction tools. He believes that the better the prediction, the more control you have.

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Giulio Barocco, Arch Gen Intern Med 2019, Volume 3 | DOI: 10.4066/2591-7951-C2-026

DEVELOP OF GUIDELINES FOR COLLECTIVE CATERING PUBLIC PROCUREMENT INTEGRATED WITH SUSTAINABLE DEVELOPMENT GOALS

Giulio Barocco
University of Trieste, Italy

Surveys (2015 – 2018) carried out by the local health agency of Trieste (ASUITs) in a Collective Catering (CC) sample (nurseries, schools, university, hospitals, nursing homes and workplaces) with a total daily production of 20% of the meals served in the area, have shown some critical conditions. In some CC the following has been observed: noncompliance of food supply quality and quantity; loss of up to 80% of Antiradicalic Power (ARP) and polyphenol content of several vegetable dishes, increase of more than 50% of oxidized compounds in some fish and homogenized meat dishes, as demonstrated by the University of Trieste. This represents a triple burden for the community: consumption of non-protective meals from oxidative stress; fraud of product quality/quantity (equal to 2-4% of contract value) and failure of the challenges of some of Sustainable Development Goals (SDGs). In view of these findings, ASUITs has developed recommendations and tools, which are integrated into the Consultancy Procurement Procedure (CPP), which is provided by the National Health System with LEA F6. These recommendations and tools take into consideration: the analysis of item costs; merceological food value; working conditions and the indications of the Ministry of Health for CC that provide adoption of the Nutrient Analysis Critical Control Points (NACCP) process; the control and monitoring food supply quality/quantity, NACCP process; ARP and other marker to detect the nutritional value of meals. In 2018, recommendations and tools have been adopted by the International School for Advanced Studies and the area's biggest nursing home ITIS. ASUITs is involved to develop guidelines for CC public procurement with complex criteria, linked at local level to a variety of SDGs like ensure healthy lives and promote well-being for all at all ages, promoting health employment as a driver for inclusive economic growth, sustainable cities and communities, responsible consumption and production.

BIOGRAPHY

Giulio Barocco has a Master of complex actions, a graduate degree in health professions of Prevention Sciences and a Bachelor's Degree in Food Merceology. He held an expert position for the Integration and Joint Management of Food Safety and Nutrition Quality at the Public Health Agency of Trieste (ASUITS) since 2007. He is an Advisor for the development of food and nutrition projects and policies in the framework of the "Gaining Health" program (Regional Health System of the Region Friuli Venezia Giulia). He has developed several integrated programs on nutrition, food security and food safety for public institutions at local and regional level.

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HEK293-DERIVED ADENO ASSOCIATED VIRUS (AAV) PURIFICATION: COMPARISON OF SMALL-SCALE LABORATORY PRODUCTION TOWARDS INDUSTRIAL FORMAT USING MONOLITHS

Ales Strancar[1], M Tajnik Sbaizero[1], L Zentilin[2], M Leskovec[1], B Goricar[1], J Merkelj Koren[1] and **P Gagnon[1]**
[1]BIA Separations, Slovenia
[2]International Centre for Genetic Engineering and Biotechnology (ICGEB), Italy

During Recombinant Adeno Associated Virus (rAAV) downstream processing, a large amount of host-cell and product related impurities needs to be removed from the product. Successful process on laboratory scale such as Caesium chloride purification lacks scalability when the process is due to transferred to larger industrial scale. The aim of the study was to develop robust, fast and effective rAAV virus purification platform, which can be used for several AAV serotypes with various inserts. Lysed harvest and supernatant of rAAV9 were first captured and concentrated on CIMmultus™ OH column, followed by intermediate step on CIMmultus™ SO3 column and further polishing on CIMmultus™ QA column. Derived purity of industrial scale monolith purification product was compared to laboratory scale purification.

BIOGRAPHY

Ales Strancar is the CEO of BIA Separations and one of the main inventors of the CIM Convective Interaction Media® monolithic columns (new generation of chromatographic support). He is author or co-author of more than 90 scientific papers dealing with separation and purification technologies and is now one of top Slovenian Scientists. He is a co-author of five granted USA patents and their foreign equivalents, more pending, in the field of biomolecule separations and purification. As well he is a co-author of several book chapters dealing with novel chromatography technologies for biomolecule separation. He co-developed a number of industrial scale purification processes among them for Octapharma, Vienna and for Boehringer Ingelheim, Vienna.

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Note:

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MOLECULAR MECHANISMS IN SUPPORT OF ALLOGENIC PLACENTA-DERIVED STEM CELL TRANSPLANTATION WITHOUT IMMUNOSUPPRESSION

Gramignoli R
Karolinska Institute, Sweden

Placenta is a non-controversial and readily available source of stem cells for regenerative medicine. Author previously reported that human Amnion Epithelial (AE) stem cells from term placenta are not tumorigenic, have immunomodulatory and anti-inflammatory properties. In preclinical and clinical studies, AE engrafted and survived without administration of immunosuppressive drugs, resulting in correction of metabolic diseases or reversal of acute and congenital diseases. During the past years he studied and identified molecular pathways driving AE immune regulatory capacity. He performed surface screening of AE cells, profiling all the molecules commonly described on stem and somatic cells. Amnion characteristically lacks HLA-II expression and expresses HLA-Ia and non-polymorphic HLA-Ib (responsible for maternal immune-toleration of the fetus). He quantified the level of expression of HLA-Ib molecules both as membrane-bound and soluble forms and he quantified the level of expression of all known plasma membrane nucleotidases, recently identified as important regulators in immune cell response. AE cells constitutively express all ecto-enzymes and their activity was confirmed on purified immune effector cells (T-, B- and NK-cells). He concluded that high level expression of ecto-enzymatic axis and HLA-G plays a key role in immunological tolerance and long-term acceptance of the human xeno-cell graft in immune-competent mice. The ability to treat the most common (liver) diseases with one stem cell therapy without the administration of immunosuppressive drugs could be a "game-changer" and will greatly expand the number of patients who could benefit from cellular therapies. Based on AE safety and successful preclinical transplants, approval was granted to begin banking AE cells under cGMP condition at Karolinska Institute and to perform AE transplants on 10 patients with liver disease.

BIOGRAPHY

Gramignoli R is specialized in medical genetics and has a PhD in Molecular and Translational Medicine. During his post-graduate studies at University of Pittsburgh, he identified and proposed new solutions for roadblocks limiting clinical hepatocyte transplantation. Due to the paucity of human hepatocytes, he investigated alternative sources, such as iPS and placental stem cells. Working with his Mentor Dr Strom, they became the first group to get approval for isolation and clinical infusion of human hepatocytes and Amnion Epithelial (AE) stem cells. Over the past years, they have accumulated evidences on the potential of AE cells in several models of congenital liver diseases and as supporting therapy in fulminant hepatic failure. Based on safety and efficacy, in addition to AE immunomodulatory and anti-inflammatory effects, they are in the process to start a phase I/IIa clinical trial for liver disease and to create the first placenta stem cell bank.

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Note:

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THINKING INSIDE THE BOX: CENTRALIZED VS DECENTRALIZED MANUFACTURING

Vered Caplan
Orgenesis Inc., Israel

Cell therapy refers to the injection of cells to cure various diseases. Cell therapy is a rapidly growing field in medicine that can aim to treat different diseases such as diabetes, liver diseases, immuno-oncology, cardiology, dermatology and autoimmune disease. The cell therapy industry needs to overcome major challenges before the developed therapies can be brought to patients worldwide. There is a high demand to satisfy patient needs and the manufacturing technology lacks the capacity to meet this urgency. In addition, there is currently a tremendous burden of cost associated with cell and gene therapies like CART, because these treatments are being manufactured at offsite CMOs. Finally, the regulatory process is long, expensive and complicated. There is a great need for a custom-made approach that is tailored to the specific requirements of clients and designed to ensure short lead times with competitive costs, in order to bring state of the art therapies to the market. Orgenesis is establishing a one-stop-shop point of care service for hospitals to bring these therapies in a cost effective, high quality and scalable manner to patients. The organization is leveraging IP, technical expertise and know-how. The platform allows a modular cell production cGMP closed system platform for the development of early stage products. Author's vision is providing the pathway for cell and gene therapies to cure disease, by furthering the research and development of technologies throughout the world.

BIOGRAPHY

Vered Caplan was the Chief Executive Officer of Orgenesis Inc. since August 14, 2014. She has an MSc in Biomedical Engineering from Tel-Aviv University specializing in Signal Processing; Management for Engineers from Tel-Aviv University specializing in Business Development and a BSc in Mechanical Engineering from the Technion-Israel Institute of Technology specialized in software and CAD systems. Throughout her managerial career, she served as CEO of several biotechnology such as: Interim (President and CEO), since 2008, she was Chief Executive Officer of Kamedis Ltd., From 2004 to 2007, she was Chief Executive Officer of GammaCan International Inc., During the previous five years, she has been a director of the following companies: Opticul Ltd., Inmotion Ltd., Nehora Photonics Ltd., Ocure Ltd., Eve Medical Ltd., and Biotech Investment Corp.

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QUALITY OF LIFE FOR CHILDREN WITH CYSTIC FIBROSIS IN GAZA STRIP

Yaser M Hamdouna
University of Palestine, Palestine

Cystic Fibrosis "CF" is a chronic, multisystem genetic disease which results in chronic respiratory infections, pancreatic enzyme insufficiency and associated complications in untreated patients. Descriptive, analytical and cross sectional design was used in this study. The study involves 36 children with CF (less than 12 years old) in Gaza. The researchers uses a questionnaire, which included demographic, illness related variables and quality of life domains (physical, emotional, social and school). Reliability coefficient for the questionnaire "Cronbach alpha" was measured and was 0.833. About 61% of the study population was males and 39% were females. Approximately 47% of them were less than 9 years and 53% were more than 9 years. Housing classification was 38.9%, 33.3% and 27.8 % for property house, renting house and family house respectively. Most of their parents had low educational levels and the majority of them was unemployed and has a monthly income less than 1200 NIS. Results also showed that about 61% of them have another sibling with CF. The majority of them receive Creon at a regular basis. This study also showed that the most common associated disease among children was respiratory problem with 43.2%. Also, 38.3% of them had gastrointestinal disease, 14.8% had heart disease and 3.7% had diabetes mellitus. The overall perception of the children regarding QOL was 55% which was considered low. The social functions was the highest (61.6%), physical functions (55.2%), school function (50.6%) and emotional function (48.8%). It is also clear that QOL in males were more than females but this difference was not statistically significant. Results also showed a positive correlation with a highly significant difference between QOL and the four domains and between domains with each other. Social performance was high correlated with school performance (r = 0.706) while the lowest correlation was between physical and school performance with no significant (p-value =0.065). The study recommends the importance of initiating a program to enhance the QOL for children with CF and focusing on the emotional and psychological aspects for those children as it was the least one perceived. Also, there should be coherent and integrated psychosocial programs for children with CF in Gaza strip since this will improve their QOL and will revealed more positive clinical aspects which will in turn improve their health status and will delay the occurrence of complications and life threatening situations.

BIOGRAPHY

Yaser M Hamdouna works in the University of Palestine located in Palestine, his research interests are involved around the public health mainly involving the children and their health.

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FUNCTIONAL DISORDERS, VASCULAR RISKS AND MALIGNANT DISEASES. PREVENTION BY SUBJECTIVE LOWERING OF PREPRANDIAL BLOOD GLUCOSE (BY PLANNING AND RECOGNIZING INITIAL HUNGER)

Mario Ciampolini
University of Florence, Italy

We recently described the training of the passage from scheduled to demanded meals in infants and adults. Reduction in energy intake was obtained by subjectively abolishing conditioned meals and by administering food only after demand by the infant or after hunger perception by the adult (Initial Hunger Meal Pattern; IHMP). Conditioned meals were those scheduled and/or presented to the infant as well to the adult by sight, smell, mentioning, gesturing or simply at a fixed mealtime. In contrast IHMP training consisted of meal suspension and of feeding after the first infant's demand or after an adult's self-noticing arousal of hunger. IHMP was checked by measuring mean blood glucose before three meals per day for a week (MBG) and was associated with significant decreases in diary-reported energy-intake, MBG, glycated hemoglobin, body weight, insulin AUC in glucose tolerance tests and in days with diarrhoea as compared to randomized control subjects who maintained conditioned meals. Although generalized, conditioned eating is a modern aberration that is associated with development of insulin resistance and overall inflammation. These associations are well demonstrated independently from the implicated mechanism. A state of overall subclinical inflammation greatly increases cell and DNA replications and replication errors. After decades of DNA errors, oncogenic cells arise and cumulate. A prevention of malignancies is possible by interrupting the development of conditioned eating, insulin resistance and associated overall inflammation.

BIOGRAPHY

Mario Ciampolini is a retired professor from University of Florence, Department of Paediatrics. He is the Emeritus member of the society for the study of ingestive behavior and of ASN (American Society for Nutrition), member of the Academy of Sciences of India Union. Two Children from Vanna Pastacaldi: Iacopo, orthopedic surgeon, director of a hospital in Sommerset (UK) and Lorenzo, PhD in electronic engineering, currently in the management of ST Microelectronics (Grenoble, FR). He made humanistic studies during the first seven years after graduation and wrote two Italian books: Human differences and a study on Renassaince. Human differences he (born 1933) directed the gastroenterology Research Unit, a third level referral center in the department of Pediatrics of the University of Florence (Meyer hospital) from 1965 to 2000. In Tuscany first he diagnosed celiac disease by the Watson capsule. He worked at the Cornell University for a joined research with the University of Florence on energy expenditure in children. A long term strategy was designed with Giuliano Parrini, prof. of physics (Florence, It), Andrea Giommi, prof. of statistics (Florence, It) and Cutberto Garza, Boston College, Rector. Three students came from Amsterdam Medical Center to learn "Initial Hunger (IH)". The unit published 150 scientific articles, more than 50 in international Press. His main achievements are Hunger can be taught; and an initial hunger meal pattern can be constructed (IHMP = Three IH arousals per day). IHMP decreases energy intake, mean pre-prandial BG, body weight, insulin resistance and fecal energy loss. The sequence of 21 pre-prandial BG measurements in a week (Mean BG) is stable and comparable through months in the single individual and stratified in population.

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Alejandra Meléndez González, Arch Gen Intern Med 2019, Volume 3 | DOI: 10.4066/2591-7951-C2-026

PROPOSAL OF A REFERENCE PATTERN FOR NUTRITIONAL EVALUATION IN NURSERIES CHILLAN, 2012

Alejandra Meléndez González
Medical University of the Americas, Chile

Chile initiated the health reform process in 2000, which has required an up-to-date diagnostic to evaluate and reformulate sectorial policies, estimate the demand that the health system will face and establish the corresponding epidemiological surveillance. We have used quantitative, retrospective analytical model to assess the pattern and have used 270 nurses, between 18 and 42 years old, enrolled in four health centres of the Linares district, Chile. This study identifies the parameters that allow the correct diagnosis of nutritional status in wet nurses. It evaluates the nutritional status of wet nurses from their gestation stage. Determine a mathematical system that allows the design of the reference pattern in the determination of the cut points of the Body Mass Index (BMI). Compare the results of the nutritional diagnosis obtained through three evaluation criteria: using points of cut of Body Mass Index (BMI) for the general population; cut points proposed by experts and the proposal developed in this investigation. Normality is located in the second quartile (median), a criterion also shared and used by other researchers such as Atalah in Chile and Grandi et al., in Argentina. The curve that describes the linear regression adds a clinical criterion derived from the qualitative interpretation of the data and the comparison with the proposal of the experts. It is possible to estimate a mathematical system according to the trend of the data, through the application of a linear regression model, a bio statistical numerical analysis method that allows studying the data considering all the components of the data including the bias, for this way to study the predominant behaviour of the variables under study. It is the method used (Reference Standard) to evaluate the nutritional status in Nodrizas. When comparing the results of the nutritional diagnosis, compared to the three existing assessment methods, it can be concluded that the evaluation method proposed in this research represents intermediate results between the two previous methods described (BMI according to pattern reference of the general population and Atalah and Cols.), showing a greater approach in the initial phase (before 90 days), with the proposal by Atalah and Cols., and in the final phase (before 180 days) with the cut-off points of the general population.

BIOGRAPHY

Alejandra Meléndez González is working on the project to propose a reference pattern for the assessment of nutritional status in nursing mothers in Medical University of the Americas, Chile. Her research interests are in health and nutrition studies of the wet nurses.

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SPECIAL SESSION DAY 2

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Yasmine Fakhry, Arch Gen Intern Med 2019, Volume 3
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Yasmine Fakhry

Raee Hospital, Lebanon

BIOGRAPHY

Yasmine Fakhry holds a BSC in Nutrition and Dietetics from American University of Beirut in 2008 and an MBA from Lebanese American University in 2012. She is currently the Head of Dietetics and Foodservice and HACCP team leader at Raee Hospital. She is also the coordinator of the dietetics internship program there and is a member of the following committees: Infection control, occupational health and safety and continuous education. She has more than nine years of extensive experience in both clinical and therapeutic nutrition as well as in food safety. Her interests are hospital policy and planning, healthcare marketing as well as malnutrition management. She is also a part time university instructor in public health courses. Currently, she is planning for her PhD studies.

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MALNUTRITION IN HOSPITALIZED PATIENTS BETWEEN LITERATURE AND CURRENT CHALLENGES

Malnutrition has become an alarming issue in the public health agenda worldwide. According to WHO, 1.9 billion adults are overweight or obese, while 462 million are underweight. On the other hand, 52 million children under five years of age are linked to under nutrition. Malnutrition is a direct precursor of poor health status, high healthcare expenses and high length of stay at hospital in addition to being a direct cause for morbidity and mortality. This lecture will focus on malnutrition in terms of under nutrition, wasting and cachexia in hospitalized patients from screening and assessment to management. Author will be highlighting current literature and daily challenges in Lebanese Hospital sector.