Regulatory Science

48842

Sponsor types of US interventional COVID-19 studies listed in ClinicalTrials.gov

Irene Lee, PharmD Candidate[1], Lisa Cooper, PhD[2] and Doreen Waldron Lechner, PhD[2]
[1]Rutgers, The State University of New Jersey and [2]Department of Health Informatics, School of Health Professions, Rutgers, The State University of New Jersey

ABSTRACT IMPACT: Increase understanding of the types of sponsors responding to the COVID-19 pandemic. OBJECTIVES/GOALS: The COVID-19 pandemic has impacted millions of lives globally. To learn more about this disease and find potential diagnostic, treatment, and preventative products, the healthcare community has initiated a staggering number of clinical trials. Clinicaltrials.gov was reviewed to determine the types of sponsors who are conducting COVID-19 studies. METHODS/STUDY POPULATION: Clinicaltrials.gov was searched using terms 'COVID-19' and 'SARS-Cov-2'. Search results were further defined to include only 'Interventional' studies. Of these, only studies with sites located in the United States were selected and for which the 'Condition' included at least one of the following terms: 'COVID', 'COVID-19', 'Coronavirus', 'SARS-Cov-2', 'SARS', or '2019-nCoV'. Study sponsors were then categorized as: (1) commercial, (2) academic, or (3) other, based on 'Sponsor' information within each study listing. A Google search was conducted for any sponsor that was not easily categorized to obtain additional information to support the proper assessment of sponsor type. The types of sponsors were analyzed over time using the 'First Posted' date of each study listing. RESULTS/ANTICIPATED RESULTS: A total of 3662 studies were retrieved, of which 2075 were 'Interventional' studies. The studies were further reduced to 681 studies by including only United States sites and the desired 'Condition'. The percentage of studies from this refined dataset, by sponsor type, were found to be 63% academic, 34% commercial, and 3% other. The relationship between time and sponsor type demonstrated that academic sponsors had the highest percentage of study postings in the first month (March) of the COVID-19 pandemic compared to commercial and other sponsors. Following this first month, academic study postings gradually declined, while commercial sponsors had an increase in postings per month into July, followed by a gradual decline. Few other sponsor type postings were made and occurred primarily in August. DISCUSSION/SIGNIFICANCE OF FINDINGS: The number and timing of listings may be a reflection of study intention and regulatory pathway requirements. Additional variables, such as inconsistent terminology, collaborators, funding, and study start date may influence results. Further analysis may reveal how modification of listing information may result in expedited pandemic response.

Team Science

39607

Mapping the Draining Lymph Nodes in Central Nervous System Malignancies

Andrew T. Coxon[1], Barry A. Siegel[2], Tanner M. Johanns[3] and Gavin P. Dunn[1]
[1]Department of Neurological Surgery, Washington University School of Medicine, [2]Division of Nuclear Medicine, Mallinckrodt Institute of Radiology, Washington University School of Medicine and [3]Division of Medical Oncology, Washington University School of Medicine

ABSTRACT IMPACT: We seek to determine which lymph nodes drain the human brain. OBJECTIVES/GOALS: Lymphatic vessels train lymphatic fluid from the central nervous system (CNS), but the specific lymph nodes that these vessels drain to remains unknown in humans. We intend on using technetium tilmanocept (TcTM)to map the draining lymph nodes of the CNSin humans. METHODS/STUDY POPULATION: Patients having a tumor resected are eligible for the trial. All patients will have TcTM injected intracranially after tumor resection. Six patients will be enrolled in Cohort 1 to define the time course of drainage to the lymph nodes. Patients in Cohort 1 will be imaged with planar LS within 7 hours of injection and the following day. Either 12 or 24 patients will be enrolled into Cohort 2 to localize the draining lymph nodes with SPECT-CT. The optimal imaging timepoint from Cohort 1 will be used for Cohort 2. Patients in Cohort 2 will be stratified depending on if their tumor is in the frontal, parietal, occipital, or temporal lobe. RESULTS/ANTICIPATED RESULTS: We anticipate that we will detect TcTMin the deep cervical lymph nodes after injection into the brain. It is unclear exactly which lymph nodes the tracer will go to. We hypothesize that the results among patients will be similar, but interindividual variation is a possibility. Furthermore, patients with disease in different lobes of the brain may have different lymph drainage patterns. DISCUSSION/SIGNIFICANCE OF FINDINGS: We seek to answer a fundamental question of human anatomy: what lymph nodes drain the human brain? Additionally, knowing which nodes drain the human brain could shape future research of immunotherapy in patients with brain cancer or autoimmune disease such as multiple sclerosis.

Translational Science, Policy, & Health Outcomes Science

54770

A Comprehensive Online Platform for Plain Language Clinical Trial Result Summary Development

Christian Reyes
University of Southern California

ABSTRACT IMPACT: This work will impact participants of clinical trials by better informing them of their trial's results and their important role within the clinical research process. OBJECTIVES/GOALS: This project aims to equip researchers with an online tool for the development, dissemination, and collection of participant feedback for plain language clinical trial (CT) result summaries (PLCTRS). PLCTRS ensure that participants fully understand their trial's results and their role in the CT process. METHODS/STUDY POPULATION: This online development platform is a web application made with CSS, HTML, and JavaScript. First, general trial identification information including study aims and eligibility will be input by researchers. Then, they will be prompted with tips and suggestions for composing in plain language and to ensure inclusion of all essential trial information. Next, the platform will disseminate this writing electronically to participants. Participants then provide meaningful feedback on the platform about their comprehension for the researcher, which the platform will aggregate and summarize for revisions. This process of drafting and feedback is repeated until a satisfactory PLCTRS is finalized. RESULTS/ANTICIPATED RESULTS: The anticipated results of this project are overall improved comprehension of clinical trial results by participants. This comprehension will be measured by participants ability to answer certain questions not only regarding trial outcomes, but also about the trial in general. For instance, before and after interacting with the

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PLCTRS, trial participants will be asked if they can identify which investigational drug was being studied and its possible side effects. This project could anticipate identification of trial elements and results deemed difficult to comprehend by participants; thus they would be better informed after interacting with the platform. DISCUSSION/SIGNIFICANCE OF FINDINGS: This project will ensure that participants better comprehend the trials they participated in beyond the required informed consent process - which only covers their comprehension prospectively. This project seeks to address the gap of ensuring participant comprehension retrospectively.

57437

Effects of Prebiotics on the Gut Microbiome Profile, Beta-cell Function and Immune Markers in Newly-Diagnosed Type 1 Diabetes

Heba M. Ismail, Carmella Evans-Molina and Linda A. DiMeglio
Indiana University School of Medicine

ABSTRACT IMPACT: The proposed research study will provide critical pilot data on the effect of using the prebiotic (HAMS-AB) on the gut microbiome profile, Beta-cell function and immune markers in humans with T1D. OBJECTIVES/GOALS: The overall objective of this study is to assess how the prebiotic high amylose maize starch that has been acetylated and butyrylated (HAMS-AB) impacts the gut microbiome profile, short chain fatty acid (SCFA) production, glycemia, Beta-cell function/health and immune responses in newly diagnosed youth with type 1 diabetes (T1D). METHODS/STUDY POPULATION: We are performing a pilot randomized cross-over trial. We plan to recruit 12 newly-diagnosed T1D youth with residual Beta-cell function between 12-16 years of age. We will profile the gut microbiome using metagenomics, measure stool SCFA levels using mass spectrometry, assess glycemia using continuous glucose monitoring, assess insulin production using mixed meal tolerance testing, assess Beta-cell stress using proinsulin/C-peptide levels, and test immune responses by examining cytokine levels and frequency, phenotype and function of T cell markers in peripheral blood. RESULTS/ANTICIPATED RESULTS: Thus far, we have enrolled 3 participants, 1 has completed the study. Baseline assessments indicate that we have technical feasibility of performing the above studies and measurements. Recruitment and enrollment are ongoing. We hypothesize that the use of HAMS-AB in newly diagnosed youth with T1D will (i) improve the gut microbiome profile, (ii) increase SCFA production, (iii) improve overall glycemia and Beta-cell function and (iv) modulate the immune system and mitigate autoimmunity. DISCUSSION/SIGNIFICANCE OF FINDINGS: Given the failure to develop a cure for T1D despite multiple completed intervention studies and the unknown long-term effects of immune-modulatory therapy on those at risk for or those diagnosed with T1D, prebiotics such as HAMS-AB may offer a simple, safe, yet inexpensive and tolerated dietary alternative approach to mitigating disease.

64180

The Proportion of Young Patients with Acute Surgical Pain and Development of Opiate Abuse Disorders

Armando Uribe-Rivera, Linda Rasubala, Daniela Alvarez, Daniel Monroy-Giamundo, Hans Malmstrom and Yan-Fang Ren
University of Rochester Eastman Institute for Oral Health

ABSTRACT IMPACT: The importance of this study is to evaluate the responses following the exposure of opioid drugs in young adults to address the current opioid epidemics OBJECTIVES/GOALS: To compare the proportion of patients between 18 and 25 years of age, who develop an opioid abuse disorder following dental surgery, to those following other surgical procedures, when an opioid drug is used for acute postoperative pain control. METHODS/STUDY POPULATION: We fashioned an IRB-sponsored retrospective cohort study of patients, ages 18 to 25 years old, who presented for dental surgery or other medical surgical procedures, at Strong Memorial Hospital Medical Center, at the University of Rochester and received opioid drug treatments, for acute surgical pain management. Patients with the diagnosis of acute surgical pain were included in the study. However, those with chronic pain or other related abnormalities were excluded, even if a diagnosis of acute surgical pain was present in the electronic chart. The clinical data were retrieved from electronic medical records and NYS-iStop records. All statistics were significant at the level of <0.1 RESULTS/ANTICIPATED RESULTS: We identified 167 subjects, of whom, only 150 subjects met inclusion criteria (n=100) in dentistry and (n=50) in other medical specialties. Patients were followed up in a 7-year period. Most of the subjects were females (n=91), Caucasian (n=80), and lived in a suburban location (n=78). The most frequently prescribed opioid included hydrocodone (n=119). A significantly higher proportion (8.7%) of patients developed opioid abuse disorders in the control group, compared to 1% of subjects in the experimental group (p 0.02). Those in the control group received marginally significant higher doses of MMEs 447.2 +/-644.8 mg vs 306.2 +/-354.7mg in the experimental group (p 0.086). Those in the control group had significantly longer periods of opioid treatment 10 (+/-12) compared to 6(+/-6) days in the experimental group DISCUSSION/SIGNIFICANCE OF FINDINGS: It is paramount to evaluate the morphine milligram equivalents, and duration of opioid treatment given to the young population with acute surgical pain, to prevent opioid abuse disorders in this vulnerable cohort.

70400

Collaborative Care for Opioid Dependence And Pain (CCODAP): A Pilot Randomized Control Trial of an Opioid Tapering Intervention

Michael Bushey and Kurt Kroenke
Indiana University School of Medicine

ABSTRACT IMPACT: If successful, this program can provide a scalable, patient-centered intervention to help patients taper off opioid medications in primary care settings. OBJECTIVES/GOALS: Tapering of chronic opioid therapy is often desirable but challenging in primary care and specialty clinics that lack behavioral health expertise. The objective of this pilot study is to determine the feasibility of testing a peer-delivered pain self-management program to assist primary care patients through an opioid taper. METHODS/STUDY POPULATION: To provide critical support to patients and providers during opioid medication tapering, we propose to conduct a 40 patient randomized controlled pilot of a 12-week telecare collaborative care program administered by a psychiatrist and peer recovery specialist team. The intervention will incorporate a validated positive psychology intervention for treating chronic pain. Additionally, participants will be invited to participate in semi-structured individual interviews to discuss their experience in the trial, what worked well, what could be improved, and potential strategies to bolster recruitment of additional patients in future studies. RESULTS/ANTICIPATED RESULTS: Our primary aim is to determine the effectiveness of our intervention in facilitating opioid medication weaning, with reduction in opioid dose as the primary outcome. Our secondary aims will be to assess pain outcomes, adherence to tapering, patient satisfaction, and barriers to adherence as described by patients.

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