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

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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

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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

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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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DISCUSSION/SIGNIFICANCE OF FINDINGS: This trial proposes a novel collaborative care approach for opioid weaning using proven, easy-to-deliver positive psychology tools for pain management that, if successful, could be implemented broadly in many clinics struggling to safely reduce opioid prescribing.

73936

Developing a Patient-Rated Outcome Measure of Alcohol and Drug Craving: A Systematic Review

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ABSTRACT IMPACT: The findings from this study will inform the development of an FDA-approved patient-rated outcome measure of drug and alcohol craving that can be used in clinical trials aimed at developing or testing effective treatments for substance use disorder. OBJECTIVES/GOALS: Craving is a potential target of investigative medications to reduce drug use due to the strong link between craving and drug use. We will identify all existing craving measures as the first step for developing an FDA-approved patient-rated outcome measure for use in clinical trials. METHODS/STUDY POPULATION: Following PRISMA guidelines, we will update Rosenberg's (2009) craving review by conducting a systematic review of all existing published and unpublished measures of craving for alcohol, nicotine, cannabis, opioid, and stimulant use. Electronic database (i.e., Ovid MEDLINE, Embase, PsycINFO, Web of Science, Cochrane), forward, backward, and author searches will be conducted. We will also request unpublished craving measures on major listservs (e.g., Research Society on Alcoholism, the Collaborative Perspectives on Addiction, and the College on Problems of Drug Dependence). All papers included in Rosenberg's (2009) review through September 2020 will be included. RESULTS/ANTICIPATED RESULTS: The findings from this review will provide a comprehensive summary of the construct of craving and its hypothesized and tested domains. This review will elucidate whether the literature suggests there are components of craving unique to alcohol, nicotine, cannabis, opioid, and/or stimulant use, and whether there are key elements of craving common across the disorders. Therefore, these findings will inform whether a single patient-rated outcome measure of craving can be developed for use across substances or if unique patient-rated outcome measures of craving need to be developed for each substance. DISCUSSION/SIGNIFICANCE OF FINDINGS: While many different measures of craving exist, none have gone through the developmental steps required to qualify as an FDA-approved patient-rated outcome measure on which drug treatment labeling can be based. Completing this systematic review is the first step in this process.

77286

Intravital microscopy in the study of the tumor vasculature of patients with peritoneal carcinomatosis

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ABSTRACT IMPACT: Investigation of tumor-associated blood vessels may serve as an imaging biomarker of response to systemic therapy and cancer outcomes. OBJECTIVES/GOALS: Aberrancies in the tumor microvasculature limit the systemic delivery of anticancer agents, which impedes tumor response. Using human intravital microscopy (HIVM), we hypothesized that HIVM would be feasible in patients with peritoneal carcinomatosis (PC) and generate clinical utility. METHODS/STUDY POPULATION: During cytoreductive surgery with hyperthermic intraperitoneal chemotherapy for PC, HIVM was performed in both tumor and non-tumor areas. The primary outcome was HIVM feasibility to measure vessel characteristics. We secondarily evaluated associations between HIVM vessel characteristics and oncologic outcomes (RECIST response to neoadjuvant therapy and disease-specific survival). RESULTS/ANTICIPATED RESULTS: Thirty patients with PC were enrolled. Nineteen patients (63.3%) received neoadjuvant therapy. HIVM was feasible in all patients. Compared to non-tumor (control) areas, PC areas had a lower density of functional vessels, higher proportion of non-functional vessels, smaller lumenal diameters, and lower blood flow velocity. Qualitative differences in these vessel characteristics were observed among patients who had partial response, stable disease, or progressive disease after receiving neoadjuvant therapy. However, no statistically significant relationships were found between HIVM vessel characteristics and oncologic outcomes. DISCUSSION/SIGNIFICANCE OF FINDINGS: These novel findings comprise the first-in-human, real-time evidence of the microscopic differences between normal and tumor-associated vessels and form the basis for our larger, ongoing clinical trial appropriately powered to determine the clinical utility of HIVM (NCT03823144).

93096

Does gender matter? Gender differences in the relationship between resting-state functional connectivity and emotion regulation in alcohol use disorder.

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ABSTRACT IMPACT: Our research has the potential to impact human health by identifying gender specific neural markers of emotion regulation in alcohol use disorder. OBJECTIVES/GOALS: Emotion dysregulation is known to be mediated by altered functional organization of the limbic system in addiction. This preliminary study sought to identify gender effects in the association between emotion regulation and resting-state functional connectivity (rsFC) of a negative affect network. METHODS/STUDY POPULATION: 55 individuals receiving treatment for alcohol use disorder (~2 weeks of abstinence) were recruited for this study and included in this analysis (N=55; Age: M=41.78, SD=10.66; 21 females). RsFC within a network involved in the withdrawal/negative affect stage of addiction and Personality Inventory for DSM-5 (PID-5) metrics were collected from all participants. RsFC data were preprocessed using the Human Connectome Project pipelines. Correlations between (a) rsFC within the withdrawal/negative affect network and the (b) scores of the negative affect subscale of the PID-5 instrument were conducted for each gender separately. RESULTS/ANTICIPATED RESULTS: Independent samples t-test showed a statistically significant gender difference in the PID-5 negative affect

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