the study conduct timeline. METHODS/STUDY POPULATION: This study compares twenty Phase 1 COG Pilot and Phase 1 Consortium trials that employed the Rolling 6 design with hypothetical results under the assumption that a 3+3 design had been executed. The number of evaluable patients required to complete the study, number of DLTs, number of inevaluable patients, overall study duration, time suspended to enrollment (i.e., waiting for DLT evaluation), and DLT risk are compared between study designs using Wilcoxon's signed rank test. RESULTS/ANTICIPATED RESULTS: The Rolling 6 study design required less time to complete the studies compared with 3+3 design (median 273 vs. 297 days, P = 0.01). In general, the Rolling 6 study design required more patients, had more inevaluable patients, and there were more dose limiting toxicity (DLT) events. However, there was no significant difference in DLT risk (median 0.15 vs. 0.17, P = 0.72). DISCUSSION/SIGNIFICANCE OF IMPACT: The Rolling 6 study design effectively shortens the study conduct timeline compared with the traditional 3+3 design for Phase 1 COG Pilot and Phase 1 Consortium trials without increasing the risk of toxicity.

3377

A cross-sectional analysis of opioid prescribing patterns among gynecologic oncologists using Medicare fee-for service provider utilization & payment data

David Samuel[1], Devin Miller, Sara Isani, Dennis Kuo and Gregory Gressel
[1]Albert Einstein College of Medicine

OBJECTIVES/SPECIFIC AIMS: Opioids are the first-line treatment for moderate to severe cancer-related pain. Increased awareness of opioid prescription misuse and adverse outcomes has prompted statements on their use from multiple national medical groups. In this study we characterize national-level opioid prescription patterns among gynecologic oncologists treating Medicare beneficiaries. METHODS/STUDY POPULATION: The Centers for Medicare and Medicaid Services (CMS) database was used to access Medicare Part D beneficiary data (2016). All available opioid claims prescribed by gynecologic oncologists were identified. Medication type, prescription length and other prescribing factors were recorded. Physician demographics were obtained from departmental websites and accrediting bodies. Physicians with <10 opioid claims are not included in the CMS database. Bivariate statistical analysis including chi-squared, Fisher's exact test and Wilcoxon rank-sum test were performed to compare variables with threshold for significance set at $p<0.05$. Linear regression modeling was also performed to examine association of gender with number of opioids prescribed. RESULTS/ANTICIPATED RESULTS: A total of 494 board-certified gynecologic oncologists were included in this analysis. In 2016, gynecologic oncologists wrote 23,584 opioid prescriptions for 267,824 days of treatment (average of 9.24 prescribed days per claim). The most commonly prescribed opioid was oxycodone/acetaminophen (41%). Male physicians had significantly more opioid prescription claims than females ($p<0.01$) including after adjusting for differences in years of experience. The majority of physicians had 11-50 opioid prescription claims (68%). A minority were high prescribing physicians with >100 opioid claims (11%). Of these, the overwhelming majority were male (82%) and late career (46%, >15 years since board certification). Physicians in the South had the greatest number of opioid prescription claims and significantly more than physicians in the Northeast, who had the fewest ($p<0.01$). Mean number of opioid claims increased with increasing years of experience ($p<0.05$). DISCUSSION/SIGNIFICANCE OF IMPACT: Among gynecologic oncologists, there were gender-based, regional and experience-related variations in opioid prescribing in the Medicare population in 2016. Further longitudinal studies are required to elucidate secular trends in opioid prescription practice.

3185

A Randomized Controlled Trial Comparing the Nonabsorbable Antibiotic Rifaximin vs. Dietary Intervention Low in Fermentable Sugars (FODMAP) in Irritable Bowel Syndrome

Allen Lee[1], Krishna Rao[1], Emily Haller[1], Lauren Van Dam[1], Jason Baker[1], Shanti Eswaran[1], William Chey[1], Vincent Young[1], Chung Owyang[1] and William Hasler[1]
[1]University of Michigan School of Medicine

OBJECTIVES/SPECIFIC AIMS: Objectives and goals of this study are to (i) determine whether IBS-D patients randomized to either rifaximin or low FODMAP diet show improvement in IBS-related symptoms; and (2) identify using longitudinal analyses how SIBO status and fecal microbiota features associate with response to either rifaximin or low FODMAP dietary intervention. METHODS/STUDY POPULATION: 42 patients ≥ 18 years of age who meet Rome IV criteria for IBS-D will be randomized to receive either rifaximin or low FODMAP diet intervention. The primary outcome will be the proportion of responders to intervention which is defined as ≥ 30% reduction in mean daily abdominal pain or bloating by visual analog scale compared with baseline. Exclusion criteria will include: (a) history of microscopic colitis, inflammatory bowel disease, celiac disease, or other organic disease that could explain symptoms, (b) prior gastrointestinal surgery, other than appendectomy or cholecystectomy > 6 months prior to study initiation, (c) prior use of rifaximin or formal dietary interventions for IBS-D, (d) use of antibiotics within the past 3 months, or (e) use of probiotics within 1 month of study entry. Glucose hydrogen breath tests will be performed at the beginning and end of the trial to evaluate for SIBO. Fecal samples will be collected at 0, 2, and 6 weeks to determine changes in fecal microbial composition and structure. RESULTS/ANTICIPATED RESULTS: This study seeks to examine whether longitudinal analyses of small intestinal and colonic microbiota can subtype IBS-D subjects into clinically relevant phenotypes. A total of 18 subjects have been enrolled into the study. Clinical variables, hydrogen breath test results, and fecal microbiota data are being collected for ongoing analysis. DISCUSSION/SIGNIFICANCE OF IMPACT: Results from this study may help move treatment of IBS from a purely symptom based approach to a more individualized approach by stratifying IBS-D patients into distinct clinical phenotypes which are amenable to targeted therapeutic approaches.

3065

A1BG and ITIH4 proteins are upregulated on HDL of youth with type 1 diabetes and correlate with glycemic control

Evgenia Gourgari[1], Scott Gordon, Junfeng Ma, Martin Playford, Nehal Mehta, Radoslav Goldman and Alan Remaley
[1]Georgetown - Howard Universities

OBJECTIVES/SPECIFIC AIMS: Our objective was to compare the proteomics of HDL between youth with T1DM and healthy controls

https://doi.org/10.1017/cts.2019.75 Published online by Cambridge University Press