biologic and demographic confounders and correlations from repeated OCT scans and paired eyes. RESULTS/ANTICIPATED RESULTS: Mean birthweight was 964 (SD=283) grams, mean gestational age was 27.8 (SD=2.6) weeks, 48 (51%) infants were male, and 51 (54%) were non-white. On exam, 72 (38%) eyes had blond FP, 92 (49%) had medium, and 24 (13%) had dark. OCT quality was excellent or acceptable in 725 scans (86%) and all age-appropriate retinal layers were visible in 781 scans (92%). Compared to eyes with blond FP, eyes with medium and dark FP did not have higher odds of poor/unusable OCT scan quality (adjusted OR 0.87 [95% CI 0.50-1.48] and 0.49 [95% CI 0.16-1.55], respectively) or not all age-appropriate retinal layers visible on OCT (adjusted OR 1.17 [95% CI 0.39-3.51] and 0.57 [95% CI 0.15-2.20], respectively). DISCUSSION/SIGNIFICANCE OF FINDINGS: Medium and dark FP did not impact overall scan quality or age-appropriate retinal layer visibility on investigational bedside OCT in preterm infants. This study supports the feasibility of using OCT to analyze retinal microanatomy in diverse populations of preterm infants with a range of FP.

75200

Fecal Microbiota Transplantation to Prevent Infections in Patients with Acute Myeloid Leukemia: A Double-Blind Randomized Placebo-Controlled Phase 2 Clinical Trial

Armin Rashidi, Maryam Ebadi, Tauseef Ur Rehman, Harika Nalluri, Thomas Kaiser, Shernan G. Holtan, Alexander Khoruts, Daniel J. Weisdorf and Christopher Staley
University of Minnesota

ABSTRACT IMPACT: By restoring the gut microbiota in patients with acute myeloid leukemia exposed to antibiotics, we will reduce infections during and after curative-intent chemotherapy. OBJECTIVES/GOALS: Infection is a leading cause of death in acute myeloid leukemia (AML). Antibiotics disrupt the gut microbiota, promoting secondary infections. Through a double-blind randomized placebo-controlled phase 2 trial, we will determine whether microbiota restoration using fecal microbiota transplantation (FMT) prevents infections in AML patients. METHODS/STUDY POPULATION: 72 intensively treated AML patients at our institution are randomized in a 2:1 ratio to FMT (arm A) or placebo (arm B). After completing each course of antibacterial antibiotics, patients receive one study treatment. Up to 3 study treatments are administered over 3 months. FMT is delivered as a third-party oral product containing microbiota (~5x10^11 bacteria) in 4-6 capsules. Stool samples are collected before and after each study treatment. The primary endpoint is 4-month overall infection rate. 16S rRNA gene sequencing of stool samples is used to determine specific taxa that are under- or over-represented in samples preceding infections and compare the two arms for key microbiome features including diversity and composition. Bloodstream infection within 7 days after FMT counts towards stopping rule. RESULTS/ANTICIPATED RESULTS: Five patients have been enrolled: 4 have received 1 dose and 1 received 2 doses. The only adverse event (possibly related to study treatment) has been grade 1 abdominal pain in 1 patient. Notably, no bloodstream infection has occurred. All planned samples have been collected and are sequenced in batches. We expect arm A patients to experience fewer infections and fewer intestinal blooms of pathobionts, and both arms to experience intestinal blooms before specific infections. An interim efficacy analysis will be performed at half total enrollment. DISCUSSION/SIGNIFICANCE OF FINDINGS: Current supportive care during intensive chemotherapy is fundamentally anti-microbial and results in dysbiosis, with detrimental consequences. We will establish the evidence for FMT as a restorative strategy in AML patients. This is the first randomized placebo-controlled trial of repeated FMT, with potential implications to other cancers.

88116

Effect of conjugated estrogens and bazedoxifene on glucose, energy and lipid metabolism in obese postmenopausal women

Kara Marlatt[1], Dragana Lovre[2], Robbie Beyl[1], Chandra Tate[2], Evelyn Hayes[3], Charles Burant[4], Eric Ravussin[1] and Franck Mauvais-Jarvis[2]
[1]Pennington Biomedical Research Center, [2]Tulane University Health Sciences Center, [3]Baton Rouge General Hospital and [4]University of Michigan

ABSTRACT IMPACT: A short treatment of 8 obese postmenopausal women with conjugated estrogens and bazedoxifene does not alter insulin sensitivity or ectopic fat but increases serum markers of hepatic de novo lipogenesis and production of triacylglycerides. OBJECTIVES/GOALS: Combining conjugated estrogens (CE) with the selective estrogen receptor modulator bazedoxifene (BZA) is a novel, orally-administered menopausal therapy. We investigated the effect of CE/BZA on insulin sensitivity, energy metabolism, and serum metabolome in postmenopausal women with obesity. METHODS/STUDY POPULATION: We conducted a randomized, double-blind, crossover pilot trial, testing the effect of CE/BZA on cardiometabolic health in postmenopausal women. Eight postmenopausal women (age 50-60 y, BMI 30-40 kg/m2) were randomization to an 8-week CE/BZA or placebo treatment separated by an 8-week washout period [NCT02274571]. The primary outcome was insulin sensitivity (hyperinsulinemic-euglycemic clamp), while secondary outcomes included body composition (DXA); resting metabolic rate (RMR); substrate oxidation (indirect calorimetry); ectopic lipids (1H-MRS); fat cell size, adipose and skeletal muscle gene expression (biopsies); inflammatory markers; and serum metabolome (LC/MS). RESULTS/ANTICIPATED RESULTS: CE/BZA had no effect on insulin sensitivity, body composition, ectopic fat, or substrate oxidation, but resulted in a non-significant increase in RMR (basal: p=0.06; high-dose clamp: p=0.08) compared to placebo. CE/BZA increased serum high-density lipoprotein cholesterol. CE/BZA also increased serum diacylglycerol (DAG) and triacylglycerol (TAG) species containing long-chain saturated, mono- and polyunsaturated fatty acids (FAs), and decreased long-chain acylcarnitines. These findings possibly reflect increased hepatic de novo FA synthesis and esterification into TAGs, and decreased FA oxidation, respectively ($p<0.05$). CE/BZA increased serum phosphatidylcholines, phosphatidylethanolamines, ceramides, and sphingomyelins, possibly reflecting the increase in lipoproteins ($p<0.05$). DISCUSSION/SIGNIFICANCE OF FINDINGS: A short treatment of postmenopausal women with CE/BZA did not alter insulin action or ectopic fat, but increased markers of hepatic de novo lipogenesis and TAG production. Study limitations include a small sample size and short treatment period. A larger, fully powered study is needed to validate the potential metabolic benefit of combining CE with BZA.

https://doi.org/10.1017/cts.2021.497 Published online by Cambridge University Press