For more information, stop by the Conquering Diseases office. We are open 8:00 AM – 4:00 PM.

September 2016

Studies of interest

**Non-Alcoholic Steato-Hepatitis (NASH) Study (Docket # H-0008884)**
The REGENERATE Study: A phase 3 double-blind, randomized trial for subjects with Non-Alcoholic Steato-Hepatitis (NASH), a type of fatty liver disease. Eligible subjects will be randomly assigned to receive one of two different doses of Obeticholic Acid (OCA) 10 mg or 25 mg, or to placebo. There is an equal chance of being assigned to each of the 3 study groups. The study is long term, up to 6 years. All study drug(s) and assessments are paid for by the sponsor of the study- Intercept Pharmaceuticals. Liver biopsies are required. Contact: Donna Giansiracusa, RN at 774-441-7648 for more information.

**Primary Biliary Cirrhosis Study (Docket # H-00006939)**
The COBALT Study: A long-term study evaluating the effects of study drug, Obeticholic Acid (OCA), versus placebo on specific clinical outcomes that may be associated with Primary Biliary Cirrhosis. They may include changes in liver blood tests, changes in markers of inflammation, and other changes seen when the liver stops working effectively. Subjects have a 75% chance of receiving study drug and are expected to remain in the study for at least 2 years and up to 8 years. Participants in the study will be required to complete a screening visit to see if they are eligible to participate. Contact: Donna Giansiracusa, RN at 774-441-7648 for more information.

**Severe Acute Alcoholic Hepatitis Study (Docket # H-14851)**
NIH Study: Novel Therapies in Severe Acute Alcoholic Hepatitis study. This study will test the hypothesis that the syndrome of acute alcoholic hepatitis (AH) results from severe inflammation and dysregulation of cytokines in the setting of alcohol exposure. Further, it is hypothesized that gut derived endotoxins and other bacterial products trigger inflammation and are a consequence of increased permeability with altered gut barrier function. This study is being done to evaluate whether a combination of medications, anakinra (interleukin -1 inhibitor) plus, pentoxifylline (to protect the kidney) plus zinc, a nutrient in the diet, can treat severe alcoholic hepatitis better or more safely than standard treatment with corticosteroids. Requires subjects with recent alcohol consumption>50 g/day for >6months, with MELD ≥20 and Maddrey ≥32. Contact: Donna Giansiracusa, RN at 774-441-7648 for more information or to refer a subject.

**Are you a woman aged 35 to 64 who smokes? (Docket # 15-311)**
It is not clear how smoking affects bone health and function. Weaker bone increases risk for fracture, especially in aging women. Healthy women who smoke (35 to 64 years old), are invited to take part in a single-visit study using a low-dose x-ray to understand how smoking affects bone health. Compensation provided! For more information, please contact Joshua Johnson, PhD at 508-831-5338 or MBL@wpi.edu, or complete the survey. https://www.surveymonkey.com/r/Z895LKL
Are you interested in knowing more about your bone health? (Docket # 13-111)
Healthy women ages 21-40 are invited to participate in a research study on the effects of exercise on bone health. To be eligible for the study you must be a healthy normal body weight, non-smoker, not be pregnant or planning a pregnancy in the next two years, and must have plans to be in the Worcester area for the next two years. A four minute commitment, three times per week for one year may be required. Compensation is provided. For more information call the Musculoskeletal Biomechanics Lab at 508-831-5338, e-mail at MBL@wpi.edu, or sign up at https://redcap.wpi.edu/redcap/surveys/?s=T489XE3MHT

Heart Healthy Cooking: Tips in the Kitchen & Supermarket
This cooking class will teach you how to make smart food choices to help reduce your risk of heart disease! Renowned local Chef John Cannon will teach you how to cook a healthy meal at home for you and your family. Plus, take advantage of the opportunity to talk to a licensed, registered dietitian! This is open to anyone interested in healthy cooking. Come alone or bring your friends to learn how to prepare a heart healthy meal and then stay and enjoy the food! This is a class rather than a study.

When: September 20th
Time: 5:30 - 7:30 PM
Location: University of Massachusetts Shaw Building, 419 Belmont Street, Worcester, MA 01605

UMass Vitiligo Study Seeking Volunteers (Docket # 14848)
We are looking for people with and without the autoimmune skin disease called Vitiligo. We will collect a small sample of skin and in some cases a blood sample. We want to better understand how autoimmune diseases occur in the skin, including how immune cells choose to initiate disease as well as what causes them to enter the skin. For more information, please contact the Clinical Trials Unit at ClinicalTrialsUnit@umassmed.edu or 508-856-2800.

Sexual Dysfunction in women with Parkinson’s disease (Docket # H00009669)
Neurologists who specialize in Movement Disorders at UMass Medical School are studying the effect of Parkinson's Disease on sexual dysfunction in women. Participants will complete an anonymous questionnaire. For more information, please contact Anas Hannoun, MD at 508-334-2527 or Anas.Hannoun@umassmemorial.org.

Do you have Rheumatoid Arthritis? (Docket # H00004371)
The study will monitor the safety and effectiveness of tofacitinib (Xeljanz) and a tumor necrosis factor inhibitor (TNFi), adalimumab (Humira) in subjects with rheumatoid arthritis, comparing the incidence of cardiovascular events and malignancies. Inclusion Criteria: • Moderate to severe rheumatoid arthritis • Taking methotrexate 15mg or greater without adequate control of RA symptoms • Have at least one cardiovascular risk factor (eg, current smoker, high blood pressure, high cholesterol levels, diabetes mellitus, history of heart attack, family history of coronary heart disease). For more information, please contact Steve Ball at Steven.Ball@umassmed.edu or 508-334-0221.

Do you want help reaching your weight loss goals? (Docket #H00009012)
Participate in a research study that includes a 12-month nutrition and physical activity program. Compensation provided. Interested? Please call (508)856-1534 or e-mail study@umassmed.edu.