

The Saint Louis University Liver Center is committed to excellence in basic and clinical research. The Doisy Research Center includes laboratory space specifically devoted to liver research. These areas provide environments to improve both the understanding and the treatment of liver diseases. Our researchers include physicians as well as basic scientists in order to acquire new knowledge of fundamental liver function and causes of liver diseases as well as applicable treatments.

## **CLINICAL RESEARCH**

The division of Gastroenterology and Hepatology has one of the most active liver clinical research groups in the nation. Investigators are looking at new and innovative ways of treating liver diseases including hepatitis B, hepatitis C, liver cancer, pancreatitis, and more. Since more than 5 million people have been exposed to hepatitis C and the disease affects more than 45,000 people in the St. Louis area, numerous studies are looking at this disease and its treatment. For interest in a clinical study, call the Gastroenterology & Hepatology Clinical Research Unit at (314) 977-9400.

### **Hepatitis C**

**Protocol: 15306**

**Sponsor: GlaxoSmithKline**

**PI: Bruce R. Bacon, M.D.**

The purpose of this study is to see if a study medication is safe and effective in the treatment of thrombocytopenia (low platelet count) in subjects receiving treatment for hepatitis C.

**Protocol: 16105**

**Sponsor: Gilead GS-US-227-0106**

**PI: Adrian M. Di Bisceglie, M.D.**

A potential new treatment for preventing liver damage due to chronic Hepatitis C Virus (HCV) infection.

**Protocol: 16140**

**Sponsor: Conatus**

**PI: Bruce R. Bacon, M.D.**

To test the safety and effectiveness of a study drug taken by mouth twice daily with or without ribavirin for up to 24 weeks in patients with HCV infection to assess reduction in liver damage.

**Protocol: 15373**

**Sponsor: Romark Institute for Medical Research PI: Bruce R. Bacon, M.D.**

A study of a study medication given in combination with peginterferon  $\alpha$ -2a and ribavirin in treatment-naïve subjects with hepatitis C.

**Protocol: 15594**

**Sponsor: Schering-Plough**

**PI: Bruce R. Bacon, M.D.**

This study will compare the response rate of a study medication taken with PegIntron and ribavirin to the current standard treatment which is PegIntron with ribavirin for 48 weeks.

**Protocol: 16174**

**Sponsor Pfizer**

**PI: Bruce R. Bacon, M.D.**

The purpose of this study is to determine if adding a new study medication to the SOC treatment, increases the number of subjects whose viral load (measurement of the amount of the hepatitis virus in the blood) cannot be detected compared to those taking just standard of care treatment alone.

**Protocol: 16241**

**Sponsor: Medtronic, Inc.**

**PI: Bruce R. Bacon, M.D.**

INTRON A will be delivered subcutaneously and continuously in this research study by a pump infusion system.

### **Hepatitis B**

**Protocol: 13813**

**Sponsor: Gilead Sciences**

**PI: Adrian M. Di Bisceglie, M.D.**

To compare the efficacy of two study medications for the treatment of HBeAg positive chronic hepatitis B.

### **Hepatocellular Carcinoma**

**Protocol: 16036**

**Sponsor: Bayer HealthCare Pharmaceuticals**

**PI: Alex F. Befeler, M.D.**

The purpose of this study is to assess if a study medication in combination with TACE performed with DC beads and doxorubicin will slow down tumor growth/spread and result in increased survival in patients with unresectable (cannot be removed by surgery) liver cancer.

### **Fatty Liver – NASH/NAFLD**

**Protocol: Database**

**Sponsor: National Institutes of Health**

**PI: Brent A. Tetri, M.D.**

To investigate the etiology, natural history, diagnosis, treatment, and prevention of nonalcoholic fatty liver disease (NAFLD) as defined by steatosis, steatohepatitis, and/or fibrosis, to develop a specimen bank comprising liver tissue, serum, plasma, and DNA obtained from NAFLD subjects, and to provide a resource for clinical trials and ancillary studies of the pathogenesis, natural history, and treatment of NAFLD.

### **Pancreatic insufficiency**

**Protocol: 14687**

**Sponsor: Digestive Care Inc.**

**PI: Frank R. Burton, M.D.**

To investigate the bioavailability of pancreatic enzymes in the human upper intestine.

### **Pancreatitis**

**Protocol: MRCP**

**Sponsor: ChiRhoClin, Inc.**

**PI: Frank R. Burton, M.D.**

A multicenter study evaluating the utility of MRCP with and without study medication stimulation to study the morphology and exocrine function in subjects with chronic and recurrent acute pancreatitis.

### **Pancreatitis/ Pancreatic Cancer**

**Protocol: Endoscopy Sampling**    **Sponsor: ChiRhoClin, Inc.**

**PI: Frank R. Burton, M.D.**

To compare characteristics of samples collected for laboratory analysis via endoscopic aspiration of duodenal fluid after administration of test drug to determine if the sample is exocrine pancreas fluid in origin in sufficient volume for testing and with sufficient DNA for testing.

### **Dyspepsia**

**Protocol: FDTT**

**Sponsor: National Institutes of Health**

**PI: Charlene Prather, M.D.**

To investigate if two antidepressant medicines are more effective medicines in the treatment of functional dyspepsia than placebo (sugar pill).

### **Barrett's Esophagus**

**Protocol: Barrett's**

**Sponsor: National Institutes of Health**

**PI: Charlene Prather, M.D.**

This trial is designed to assess the effects of a study medication +/- aspirin among subjects at increased risk for adenocarcinoma of the esophagus.

### **Primary Biliary Cirrhosis**

**Protocol: 16173**

**Sponsor: Investigator Initiated**

**PI: Bruce R. Bacon, M.D.**

This study is being done to investigate whether genes (the inherited genetic material passed from parents to their children) make people more likely to develop Primary Biliary Cirrhosis (PBC).