

Clinical Research Institute Active Digestive and Liver Institute Trials

Study Title	PI	Area/Discipline
A phase 2, randomized, double-blind, placebo-controlled, 12-month, multiple-dose study to evaluate the safety, tolerability and efficacy of three dose levels of MSDC-0602K in patients with NASH (EMMINENCE™)	Barnes, Maisha	LI/Hepatology
A phase 2, dose-ranging, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics and efficacy of edp-305 in subjects with primary biliary cholangitis (pbc) with or without an inadequate response to ursodeoxycholic acid (udca)	Barnes, Maisha	LI/Hepatology
A randomized, double-blind, placebo-controlled, dose-ranging, multicenter study to assess the efficacy and safety of Rifaximin Soluble Solid Dispersion (SSD) tablets plus Lactulose for the treatment of overt hepatic encephalopathy (OHE)	Barnes, Maisha	LI/Hepatology
Radio frequency ablation in the management of pancreatobiliary disorders: A multicenter registry	Kedia, Prashant	MDI/Gastroenterology
Endoscopic sutures for gastrointestinal tract disorders: A prospective multicenter registry	Kedia, Prashant	MDI/Gastroenterology
Peroral endoscopic myotomy (POEM) for the treatment of achalasia: A retrospective and prospective multicenter registry	Kedia, Prashant	MDI/Gastroenterology
Endoscopic ultrasound (EUS) - guided endoscopic retrograde cholangiopancreatography (ERCP) in the management of pancreatic-biliary disorders: A multicenter registry	Kedia, Prashant	MDI/Gastroenterology
Efficacy, safety, and adequacy of EUS-guided liver biopsy	Kedia, Prashant	MDI/Gastroenterology
Endoscopic gallbladder drainage	Kedia, Prashant	MDI/Gastroenterology
Evaluation of safety and efficacy of NvisionVLE Imaging Low Profile system in patients with bile duct disease	Kedia, Prashant	MDI/Gastroenterology
Peroral endoscopic myotomy (POEM) for the treatment of achalasia: A retrospective registry	Kedia, Prashant	MDI/Gastroenterology
Endoscopic sleeve gastropasty	Kedia, Prashant	MDI/Gastroenterology
A humanitarian device exemption treatment protocol of TheraSpheres for treatment of unresectable primary or unresectable secondary liver cancer	Mantry, Parvez	LI/Hepatology
A long-term follow-up study to evaluate the durability of virologic response and/or viral resistance patterns of subjects with chronic hepatitis C who have been previously treated with MK-5172 in a prior clinical trial	Mantry, Parvez	LI/Hepatology
A multicenter, randomized, double-blind, placebo-controlled trial of Emricasan, an oral caspase inhibitor, in subjects with decompensated non-alcoholic steatohepatitis (NASH) cirrhosis	Mantry, Parvez	LI/Hepatology
A long-term follow-up study of subjects who participated in a clinical trial in which Asunaprevir (BMS-650032) and/or Daclatasvir (BMS-790052) was administered for the treatment of chronic hepatitis C	Mantry, Parvez	LI/Hepatology
A phase 3b, double-blind, randomized, placebo-controlled, multicenter study evaluating the effect of obeticholic acid on clinical outcomes in subjects with primary biliary cirrhosis	Mantry, Parvez	LI/Hepatology
A phase 2, pilot study of jkb-122 to assess liver tests (alt) in autoimmune hepatitis patients who are refractory or intolerant to current therapies	Mantry, Parvez	LI/Hepatology
STELLARIS: A phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Cenicriviroc in adult subjects with nonalcoholic steatohepatitis and liver fibrosis	Mantry, Parvez	LI/Hepatology
A phase 3, randomized, double-blind, placebo-controlled study evaluating safety and efficacy of bms-986036 (peg-fgf21) in adults with nonalcoholic steatohepatitis (nash) and compensated liver cirrhosis	Mantry, Parvez	LI/Hepatology
A phase 3, double-blind, randomized, long-term, placebo-controlled, multicenter study evaluating the safety and efficacy of obeticholic acid in subjects with nonalcoholic steatohepatitis	Mantry, Parvez	LI/Hepatology
A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Selonsertib in subjects with compensated cirrhosis due to nonalcoholic steatohepatitis (NASH)	Mantry, Parvez	LI/Hepatology
A 5-year longitudinal observational study of the natural history and management of patients with hepatocellular carcinoma	Mantry, Parvez	LI/Hepatology
A randomized, double-blind, placebo-controlled study to assess the safety, tolerability, and pharmacodynamics of SYN1020 in hepatic insufficiency and cirrhosis patients with hyperammonemia	Mantry, Parvez	LI/Hepatology

A phase 2, randomized, double-blind, placebo controlled study evaluating the safety, tolerability, and efficacy of gs-9674 in subjects with primary sclerosing cholangitis without cirrhosis	Mantry, Parvez	LI/Hepatology
A multicenter, randomized, double-blind, placebo-controlled phase iii study to evaluate the efficacy and safety of Elafibranor in patients with nonalcoholic steatohepatitis (NASH) and fibrosis	Mantry, Parvez	LI/Hepatology
A phase 3 clinical trial to study the efficacy and safety of the combination regimen of MK-3682B (Grazoprevir/Ruzasvir/Uprifosbuvir) in participants with chronic hepatitis c virus genotype 3 infection	Mantry, Parvez	LI/Hepatology
Outcomes in patients with hepatocellular carcinoma	Mantry, Parvez	LI/Hepatology
A phase 2, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Selonsertib, GS-0976, GS-9674, and combinations in subjects with bridging (f3) fibrosis or compensated cirrhosis (f4) due to nonalcoholic steatohepatitis (NASH)	Mantry, Parvez	LI/Hepatology
The HepQuant SHUNT Test for monitoring liver disease and treatment effects by measuring liver function and physiology	Mantry, Parvez	LI/Hepatology
Mindfulness and shared decision making pilotsStudy	Mantry, Parvez	LI/Hepatology
Establishing the normal range of fasting venous ammonia level in healthy volunteers	Mantry, Parvez	LI/Hepatology
A phase 3, double-blind, randomized, placebo-controlled, multicenter study to evaluate the efficacy and safety of obeticholic acid in subjects with compensated cirrhosis due to nonalcoholic steatohepatitis (reverse study)	Mantry, Parvez	LI/Hepatology
A Multi-Center, Randomized, Placebo-Controlled, Double-Blind Study to Confirm Efficacy and Safety of Terlipressin in Subjects with Hepatorenal Syndrome Type 1	Mantry, Parvez	LI/Hepatology
The Impact of liver cirrhosis on outcomes in trauma patients	Mantry, Parvez	LI/Hepatology
A study to evaluate the degree of steatosis in subjects with any feature of the metabolic syndrome in primary care or endocrine clinics for non-alcoholic fatty liver disease (NAFLD) utilizing vibration controlled transient elastography (vcte) and controlled attenuation parameter (CAP)	Mantry, Parvez	LI/Hepatology
Evaluation of patient preferences for shared decision making and patient-centered care	Mantry, Parvez	LI/Hepatology
Radioembolization to treat primary and metastatic liver tumors	Mejia, Alejandro	LI/Hepatology
AHPBA Registry Database	Mejia, Alejandro	LI/Hepatology
Evaluation of resection techniques of pancreatic tumors	Mejia, Alejandro	LI/Hepatology
Sofosbuvir-based regimens in hepatitis C genotype 1-patients with end-stage renal disease on hemodialysis or GFR <30mL/min	Nazario, Hector	LI/Hepatology
A randomized, double-blind, placebo controlled, 2- part, adaptive design, multicenter 12-week study to assess safety, tolerability and efficacy of LJN452 in patients with non-alcoholic steatohepatitis (NASH)	Nazario, Hector	LI/Hepatology
A phase 2, multicenter, open-label study to evaluate the efficacy and safety of Ledipasvir/Sofosbuvir in subjects with genotype 1, 4, 5 and 6 chronic HCV infection who are on dialysis for end stage renal disease	Nazario, Hector	LI/Hepatology
A randomized, double-blind, multi-dose, placebo-controlled study to evaluate the efficacy, safety and tolerability of GSK2330672 administration for the treatment of pruritus in patients with primary biliary cholangitis. (GLIMMER: GSK2330672 trial of Ibat inhibition with Multidose Measurement for Evaluation of Response).	Pagadala, Mangesh	LI/Hepatology
Phase 3, randomized, double-blind, placebo-controlled study evaluating safety and efficacy of BMS-986036 (peg-fgf21) in adults with nonalcoholic steatohepatitis (NASH) and stage 3 liver fibrosis	Pagadala, Mangesh	LI/Hepatology
A Phase 2, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Subjects with Primary Biliary Cholangitis Without Cirrhosis	Pagadala, Mangesh	LI/Hepatology
A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Selonsertib in subjects with nonalcoholic steatohepatitis (NASH) and bridging (f3) fibrosis	Pagadala, Mangesh	LI/Hepatology
Radiation-emitting SIR-Spheres in non-resectable (RESIN) liver tumor patient registry	Shahin, Islam	Interventional Radiology
Development of acute pancreatitis quality indicators	Tarnasky, Paul	MDI/Gastroenterology
Dallas acute pancreatitis protocol (DAPP)	Tarnasky, Paul	MDI/Gastroenterology

Fully covered, self-expanding metal stents (FCSEMS) for pancreatic duct strictures in patients with chronic pancreatitis	Tarnasky, Paul	MDI/Gastroenterology
Interventional radiology vs. ERC for perihilar biliary tumors: The INTERCPT Trial	Tarnasky, Paul	MDI/Gastroenterology
SpHincterotomy for acute recurrent pancreatitis (SHARP)	Tarnasky, Paul	MDI/Gastroenterology
As of : January 3, 2019		