

Testing the Use of the Usual Chemotherapy Before and After Surgery for Removable Pancreatic Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

PRE-REGISTRATION: * Pathology: Histologic or cytologic proof of pancreatic adenocarcinoma or adenosquamous carcinoma * TNM Stage: Tx-4, N0-1, M0 (M0 disease does not include spread to distant lymph nodes and organs) * Resectable Primary Tumor: Local radiographic reading must be consistent with resectable disease defined as the following on 1) arterial and venous phase contrast-enhanced abdominal/pelvic CT scan or abdominal/pelvic magnetic resonance imaging (MRI) scan and 2) chest CT: * No involvement or abutment of the celiac artery, common hepatic artery, superior mesenteric artery, or replaced right hepatic artery (if applicable) * Less than 180 degree interface between tumor and vessel wall of the portal vein or superior mesenteric vein, and patent portal vein/splenic vein confluence * No evidence of metastatic disease * Measurable disease or non-measurable disease o Non-measurable disease is defined as cytologic or histologic confirmation of adenocarcinoma of adenosquamous carcinoma by fine needle aspiration or core-biopsy of the pancreas without measurable disease by radiographic imaging REGISTRATION: * Confirmation of resectable disease by real-time central imaging review by the Alliance Imaging Core Lab at Imaging and Radiation Oncology Core (IROC) Ohio * Determined to be appropriate candidate for curative-intent pancreatectomy by surgeon intending to perform the resection * No prior radiation therapy, chemotherapy, targeted therapy, investigational therapy, or surgery for pancreatic cancer * Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic, and teratogenic effects. * Therefore, for women of childbearing potential only, a negative pregnancy test done =< 14 days prior to registration is required * Eastern Cooperative Oncology Group (ECOG) performance status 0-1 * Total Neuropathy Score < 2 * Absolute neutrophil count (ANC) >= 1,500/uL * Platelet count >= 100,000/uL * Total bilirubin =< 1.5 x upper limit of normal (ULN) (If obstructive jaundice is present, then biliary drainage must be initiated and total bilirubin =< 3.0) * Creatinine =< 1.5 x ULN OR calculated (Calc.) creatinine clearance >= 30 mL/min (Calculated using the Cockcroft-Gault equation) * No known Gilbert's Syndrome or known homozygosity for UGAT1A1*28 polymorphism * No comorbid conditions that would prohibit curative-intent pancreatectomy * Chronic concomitant treatment with strong inhibitors of CYP3A4 is not allowed on this study. Patients on strong CYP3A4 inhibitors must discontinue the drug prior to registration * Chronic concomitant treatment with strong inducers of CYP3A4 is not allowed on this study. Patients on strong CYP3A4 inducers must discontinue the drug prior to registration

Conditions & Interventions

Interventions:

DRUG: Oxaliplatin, DRUG: Irinotecan Hydrochloride, DRUG: Leucovorin Calcium, DRUG: Fluorouracil, PROCEDURE: Resection, OTHER: Questionnaire Administration

Conditions:

Pancreatic Adenosquamous Carcinoma, Resectable Pancreatic Adenocarcinoma, Pancreatic Cancer

More Information

Contact(s): Cristina R. Ferrone, MD - cferrone@mgh.harvard.edu

Principal Investigator: Fernandez, Leopoldo

Phase: PHASE3

IRB

Number: HM20023842

System ID: NCT04340141

Thank you for choosing StudyFinder. Please visit <http://studyfinder.cctr.vcu.edu> to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.