

LOCALLY ADVANCED

Clinical Trial Name: Stereotactic Body Radiation Therapy or Conventionally Fractionated Concurrent Chemotherapy and Radiation Therapy Preoperatively for Resectable or Borderline Resectable Pancreatic Adenocarcinoma (SOFT Trial)

Study Design: This study is a prospective, open-label, randomized, parallel, two-arm, phase II clinical trial. Patients meeting the eligibility criteria will be randomized after a minimum of two months of induction chemotherapy. These patients will be required to have no biopsy-proven distant disease on repeat staging studies before randomization. Patients who have radiologically equivocal evidence of distant metastatic disease (small lung nodules, or liver lesions that cannot be definitively characterized, etc.) are also eligible for enrollment. Patients with biopsy-proven metastatic disease are not eligible.

NCT#: [NCT03704662](#)

Study PI: Dr. William Hall

Research Coordinator:
Kathryn Hallada

Phone: 414-805-0124

Key Inclusion

- Confirmed, resectable/borderline resectable, locally advanced Type A pancreatic adenocarcinoma
- Patients with and without regional adenopathy are eligible
- No evidence of distant metastatic disease
- ≥ 1 cycle of systemic chemotherapy without evidence of distant progression

Key Exclusion:

- Distant metastatic disease
- Prior invasive malignancy within the last 3 years
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields
- Major surgery within 28 days prior to study entry

Clinical Trial Name: Molecular Profile-related Individualized Targeted Therapy in Resected Pancreatic Cancer with High-Risk of Cancer Recurrence (PROTECT-PANC)

Study Design: This is a prospective, open-label therapeutic interventional investigation designed to interrogate the efficacy and safety of individualized matched therapies in patients with pancreatic cancer at high risk of disease recurrence post-surgery.

NCT#: [NCT06228599](#)

Study PI: Dr. Mandana Kamgar

Clinical Research Coordinator:
Lori Keiser

Phone: 414-805-4627

Key Inclusion

- Pathologically confirmed pancreatic cancer (excluding neuroendocrine histology).
- Pancreatic tumor is surgically removed and
 - Patient has received multimodal therapy (neoadjuvant, sandwich or adjuvant chemotherapy ± radiation) or
 - Patient is ineligible for or refuses multimodal therapy
- Patient has one of the following:
 - Post-surgical cancer antigen (CA) 19-9 elevation (> 35 U/mL at least 6 weeks post-surgical resection) in the setting of bilirubin < 2 mg/dL (unless bilirubin elevation is consistent with Gilbert's syndrome) OR
 - High-risk pathological features, defined as positive surgical margin or lymph node involvement in cancer.
- Patient has no definitive measurable disease recurrence or metastatic disease at the time of first post-surgical imaging (in those with high-risk pathological features) or within four weeks of elevated CA 19-9 value as evidenced by appropriate imaging
- Laboratory values:
 - Absolute neutrophil count (ANC) ≥ 1.0 × 10⁹/L

NEW PATIENT COORDINATOR: (414) 805-6849

- Platelet count $\geq 75,000/\text{mm}^3$ ($125 \times 10^9/\text{L}$)
- Hemoglobin (Hgb) ≥ 8 g/dL
- aspartate aminotransferase (AST) serum glutamic-oxaloacetic transaminase (SGOT), alanine transaminase (ALT) serum glutamate-pyruvate transaminase (SGPT) $\leq 5 \times$ upper limit of normal range (ULN)
- ECOG Performance Status < 3
- At the time of treatment, patient should be off other anti-tumor agents for at least five half-lives of the agent or three weeks from the last day of treatment, whichever is shorter
- Patient must be presented at the Molecular Tumor Board (MTB) and agree to receive the MTB-recommended therapy

Key Exclusion:

- CA 19-9 non-producers, unless high-risk pathological features present.
- Receiving concomitant investigational agent(s) for pancreatic ductal adenocarcinoma (PDAC)
- Radiographic evidence of metastatic disease
- Inability to ingest study drugs by mouth
- Diarrheal bowel movements > 6 per day postoperatively on maximal medical therapy
- Patient has active, untreated, or uncontrolled bacterial, viral, or fungal infection(s) requiring systemic intravenous therapy
- Patient has undergone or planned major surgery other than diagnostic surgery (i.e., surgery done to obtain a biopsy for diagnosis without removal of an organ) within four weeks prior to Day 1 of study therapy
- Uncontrolled concurrent illness, including, but not limited to, unstable angina pectoris, uncontrolled and clinically significant cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements