Cancer Research Consortium of West Michigan
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FAST FACTS

ALLIANCE A021501: PREOPERATIVE EXTENDED CHEMOTHERAPY VS. CHEMOTHERAPY PLUS HYPOFRACTIONATED RADIATION THERAPY FOR BORDERLINE RESECTABLE ADENOCARCINOMA OF THE HEAD OF THE PANCREAS

Prestudy Registration eligibility criteria

Documentation of disease

- **Pathology**: Cytologic or histologic proof of adenocarcinoma of the pancreatic head or uncinate process. Diagnosis should be verified by local pathologist.

- **TNM Stage**: Tx-4, N0-1, M0*
  *M1 disease includes spread to distant lymph nodes, organs, and ascites

- **Criteria for borderline resectable disease:** Local radiographic reading must be consistent with borderline resectable cancer of the pancreatic head as defined by intergroup radiographic criteria and must meet any one or more of the following on CT/MRI:

  - An interface is present between the primary tumor and the superior mesenteric vein or portal vein and measures ≥ 180° of the circumference of the vessel wall
  - Short-segment occlusion of the SMV-PV is present with normal vein above and below the level of obstruction that is amenable to resection and venous reconstruction
  - Short segment interface (of any degree) is present between tumor and hepatic artery with normal artery proximal and distal to the interface that is amenable to resection and reconstruction
  - An interface is present between the tumor and superior mesenteric artery or celiac axis measuring < 180° of the circumference of the vessel wall

- Patients with less extensive disease than the above four (4) criteria are considered potentially resectable and are NOT eligible

- Patients with more extensive disease than the above 4 criteria are considered locally advanced and are NOT eligible.

- In addition patients with the following are considered locally advanced and are NOT eligible:
  - Any interface between the tumor and the aorta.
  - See Appendix II for additional clarification and definitions of less and more extensive disease.

Eligibility Criteria

1. **Disease Status**

   a. Confirmation of radiographic stage as borderline resectable disease by real-time Alliance central radiographic review

2. **Prior Treatment**

   a. No prior chemotherapy or radiation for pancreatic cancer

b. No definitive resection of pancreatic cancer

3. Concomitant Medications

a. Chronic concomitant treatment with strong CYP3A4 inhibitors is not allowed on this study. Patients must discontinue the drug(s) 14 days prior to registration. See Section 8.1.10 for more information.

b. Chronic concomitant treatment with strong CYP3A4 inducers is not allowed on this study. Patients must discontinue the drug(s) 14 days prior to registration. See Section 8.1.11 for more information.

4. **Medical History**

a. No grade ≥ 2 neuropathy

b. No known Gilbert's Syndrome or known homozygosity for UGAT1A1*28 polymorphism.

c. No uncontrolled gastric ulcer disease (Grade 3 gastric ulcer disease) within 28 days of registration

5. **Pregnancy and Nursing Status**

a. Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects.

b. Therefore, for women of childbearing potential only, a negative pregnancy test done ≤ 7 days prior to registration is required.

6. Age ≥ 18 years

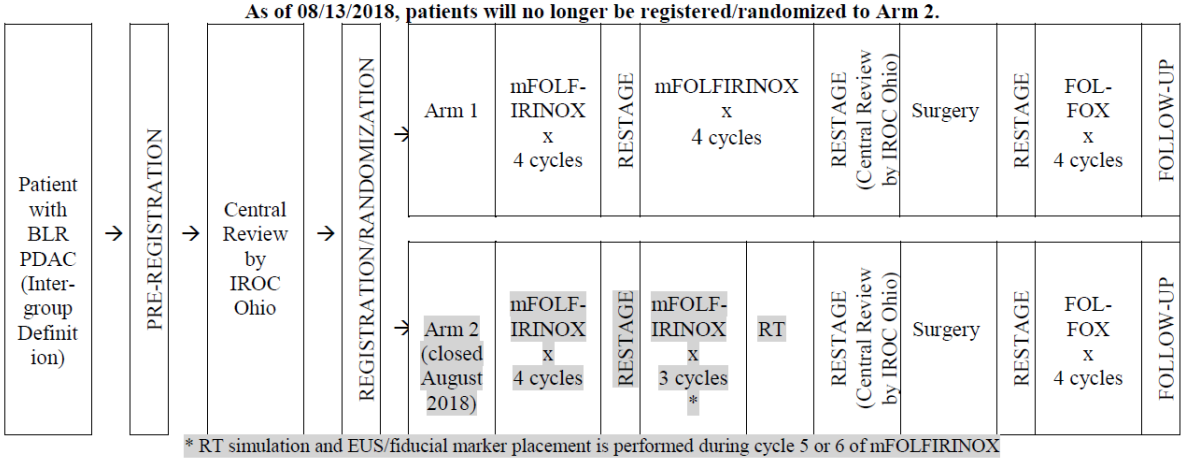
7. ECOG Performance Status 0 or 1

Required Initial Laboratory Values:

Absolute Neutrophil Count (ANC)	≥ 1,500/mm3
Platelet Count	≥ 100,000/mm3
Creatinine	≤ 1.5 x upper limit of normal (ULN)
or	
Calc. Creatinine Clearance	> 45 mL/min
Total Bilirubin	≤ 2.0 mg/dL
AST / ALT	≤ 2.5 x upper limit of normal (ULN)

Schema

As of 08/13/2018, patients will no longer be registered/randomized to Arm 2.



* RT simulation and EUS/fiducial marker placement is performed during cycle 5 or 6 of mFOLFIRINOX

Pre-study parameters

- Prior to pre-registration
  - Staging CT scan of chest or chest x-ray/CT or MRI of abdomen
- Prior to registration
  - History and physical, weight, PS
  - Pulse, BP
  - Height
  - Adverse event assessment
  - CBC, differential, platelets
  - Chemistry(Serum creatinine, electrolytes, AST, ALT, Alk, Phos, albumin, Bilirubin)
  - Pregnancy test
  - CA 19-9
  - Central Radiographic review