

FAST FACTS

ALLIANCE A021806 - A PHASE III TRIAL OF PERIOPERATIVE VERSUS ADJUVANT CHEMOTHERAPY FOR RESECTABLE PANCREATIC CANCER

On-Study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient. Physicians should consider the risks and benefits of any therapy, and therefore only enroll patients for whom this treatment is appropriate.

Physicians should consider whether any of the following may render the patient inappropriate for this protocol:

Medical condition such as uncontrolled infection, uncontrolled diabetes mellitus, or cardiac disease which, in the opinion of the treating physician, would make this protocol unreasonably hazardous for the patient.

Patients with a “currently active” second malignancy other than non-melanoma skin cancers, breast ductal carcinoma in situ, or cervical carcinoma in situ. Patients are not considered to have a “currently active” malignancy if they have completed therapy and are free of disease for ≥ 2 years.

In addition:

Women and men of reproductive potential should agree to use an appropriate method of birth control throughout their participation in this study due to the teratogenic potential of the therapy utilized in this trial. Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives or double barrier method (diaphragm plus condom).

Pre-Registration Eligibility Criteria (Step 0)

1. Documentation of Disease

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 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° 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

2. Measurable disease or non-measurable disease as defined in [Section 11.0](#).

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 Eligibility Criteria (Step 1)

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit the following page(s).

When calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test were done on a Monday, the Monday one week later would be considered Day 7.

A female of childbearing potential is a sexually mature female who: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 12 consecutive months (i.e. has had menses at any time in the preceding 12 consecutive months).

1. Disease Status

Confirmation of resectable disease by real-time central imaging review by the Alliance Imaging Core Lab at IROC Ohio.

Determined to be appropriate candidate for curative-intent pancreatectomy by surgeon intending to perform the resection.

2. Prior Treatment

No prior radiation therapy, chemotherapy, targeted therapy, investigational therapy, or surgery for pancreatic cancer.

3. 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.

4. Age ≥ 18 years

5. ECOG Performance Status 0-1

6. Total Neuropathy Score < 2 ; see [Appendix IV](#) for assessment tool example.

7. Required Initial Laboratory Values

- Absolute Neutrophil Count (ANC) $\geq 1,500/\mu\text{L}$
- Platelet Count $\geq 100,000/\mu\text{L}$
- Total Bilirubin $\leq 1.5 \times$ upper limit of normal (ULN)*
- Creatinine $\leq 1.5 \times$ ULN

OR

Calc. Creatinine Clearance $\geq 30 \text{ mL/min}^{**}$

*If obstructive jaundice is present, then biliary drainage must be initiated and Total Bilirubin ≤ 3.0 .

**Calculated using the Cockcroft-Gault equation

8. Comorbid Conditions

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

No comorbid conditions that would prohibit curative-intent pancreatectomy.

9. Concomitant Medications

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. See Section 8.1.11 for more information.

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. See Section 8.1.12 for more information.

