Cancer Research Consortium of West Michigan
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FAST FACTS

NRG-GI011: A PHASE III RANDOMIZED TRIAL OF DOSE ESCALATED RADIATION IN LOCALLY ADVANCED PANCREAS CANCER (LAPC) PATIENTS (LAP100)

REQUIRED PRE-STUDY ENTRY TREATMENT

At time of enrollment, the patient must have received 4-6 months of active chemotherapy with FOLFIRINOX (8-12 cycles) or NALIRIFOX (8-12 cycles) or gemcitabine/Nab- Paclitaxel (4-6 cycles) (1 regimen, no sequential chemotherapy). "Active chemotherapy" refers to time on chemotherapy not counting treatment breaks (i.e. if a patient had 1 month of chemotherapy followed by 1 month break, this would count as 1 month chemotherapy). Study registration must occur within 45 days of last day of chemotherapy cycle.

BASELINE PRE- ENTRY CHEMOTHERAPY REQUIREMENTS

1. **Documentation of Disease**

- Pathologically (histologically or cytologically) proven diagnosis of pancreatic ductal adenocarcinoma.

2. **Definition of Disease**

- Locally advanced unresectable disease (as defined per the National Comprehensive Cancer Network (NCCN) guidelines and institutional tumor board review).
- Patients must have baseline pre-chemotherapy scans for staging. Options include: CT chest/abdomen/pelvis, CT chest/MRI abdomen/pelvis, or CT chest/CT pelvis/MRI abdomen performed prior to enrollment.

3. **Age ≥ 18 years**

4. **Performance Status ECOG 0-2**

5. **Required Initial Laboratory Values**

- Baseline CA19-9 with a normal bilirubin level (defined as ≤ 1.2 mg/dl). AST and ALT ≤ 3x ULN.

POST PRE-ENTRY CHEMOTHERAPY REQUIREMENTS

1. **Required Laboratory Values**

- If baseline CA19-9 is elevated (defined as >37 u/mL) the post-pre-entry chemotherapy CA19-9 must be less than 37 u/mL or a 50% decline from pre-chemotherapy level with absolute value less than 100u/mL.
- If baseline CA19-9 is not elevated (defined as ≤ 37 u/mL) the post-pre-entry chemotherapy CA19-9 must remain ≤ 37 u/mL.

2. **Required Tumor Staging and Characteristics**

- No active duodenal or gastric ulcers.
- No direct tumor invasion of the bowel or stomach.
- Restaging scans showing at least stable disease (no progression). Options for scans include: CT chest/abdomen/pelvis, CT chest/MRI abdomen/pelvis, or CT chest/CT pelvis/MRI abdomen performed prior to enrollment, with restaging CT showing at least stable disease

3. **Not Pregnant and Not Nursing**

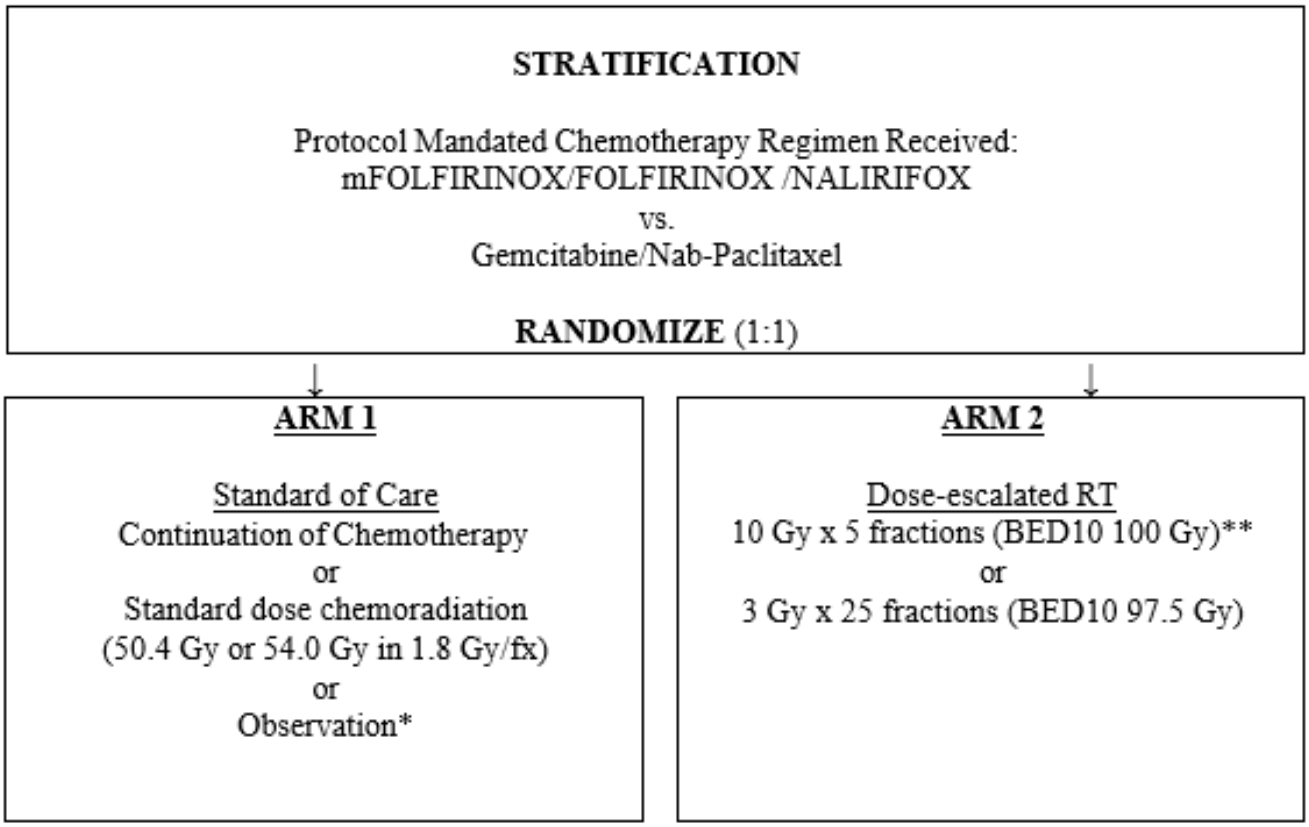
4. **Comorbid Conditions**

- No cardiac condition that was the primary reason for hospitalization in the last 6 months.
- New York Heart Association Functional Classification II or better (NYHA Functional Classification III/IV are not eligible) (Note: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification.)
- HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial.

REQUIREMENTS FOR STUDY ENTRY, TREATMENT, AND FOLLOW-UP

Laboratory and clinical parameters during treatment are to be followed using individual institutional guidelines and best clinical judgment of the responsible physician. It is expected that patients on this study will be cared for by physicians experienced in the treatment and supportive care of patients on this trial.

NRG-GI011
SCHEMA



*Suggested only for patients who have completed 6 months chemotherapy prior to enrollment.

** The default prescription is 10 Gy x 5 fractions. In situations where there is concern regarding feasibility of treating in 5 fractions, investigators must contact the Principal Investigator Dr. Nina Sanford or one of the Radiation Oncology Chairs listed on the protocol cover pages.