Cancer Research Consortium of West Michigan
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# FAST FACTS

## EA2186 - A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)

**Eligibility Criteria**

1. Patient must have newly diagnosed untreated biopsy proven metastatic adenocarcinoma of the pancreas. However, previous surgery, adjuvant chemotherapy and/or radiation therapy will be allowed, provided radiation therapy is completed at least 2 weeks prior to registration and adjuvant therapy was administered more than 6 months prior to registration. Patients with the following histology are excluded: Acinar cell; Adenosquamous carcinoma.

2. Patient must be ≥ 70 years of age.

3. Patient must have an ECOG Performance status 0-2

4. Patient must be an English speaker with the ability to understand and complete the informed consent and questionnaires

5. Patient must have adequate organ and marrow function as defined below, with results obtained within 4 weeks prior to registration:
    a. Leukocytes ≥ 3,000/mcL
    b. Absolute neutrophil count (ANC) ≥ 1,500/mcL
    c. Platelets ≥ 100,000/mcL
    d. Total bilirubin ≤ institutional upper limit of normal (ULN)
    e. AST(SGOT)/ALT(SGPT) ≤ 2.5 × institutional ULN
    f. Creatinine ≤ institutional ULN and glomerular filtration rate (GFR) ≥ 40 mL/min/1.73 m2 unless data exists supporting safe use at lower kidney function values, no lower than 30 mL/min/1.73 m2.

6. Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of registration are eligible for this protocol. HIV (+) patients who are on ritonavir or/and cobicistat-based regimen must be switched to alternative ART.

7. For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated.

8. Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load.

9. Male patients must agree not to father children while on study.

10. 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

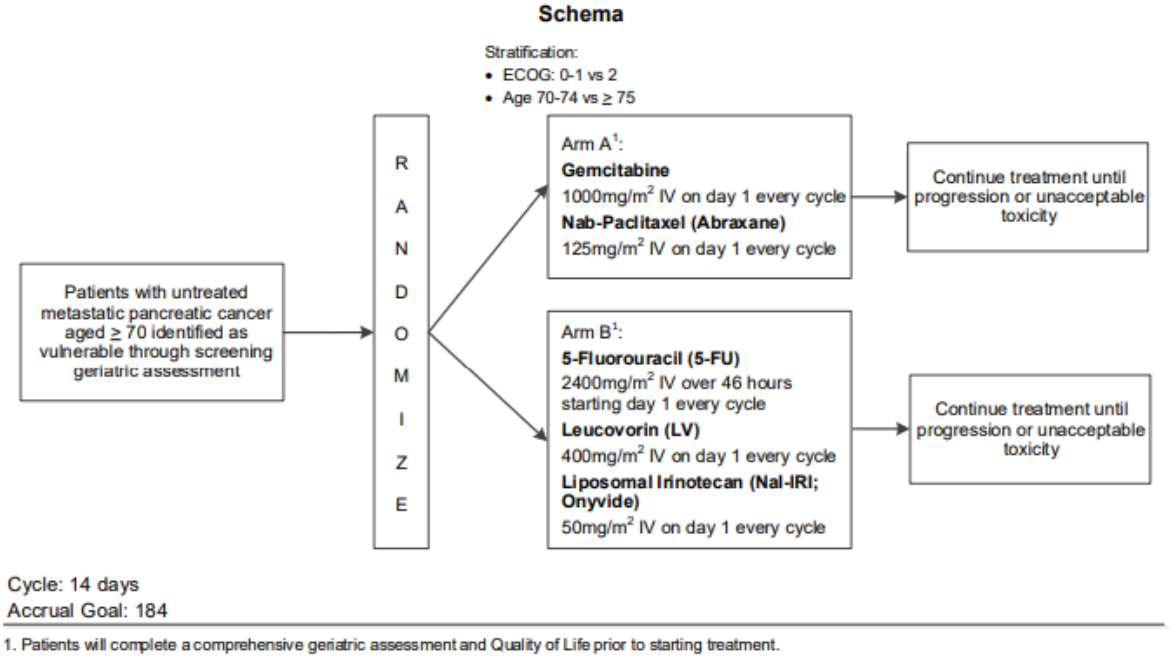
Heart Association Functional Classification. To be eligible for this protocol, patients should be class 2B or better.

11. Patient must have measurable disease as defined in Section 6.1.2 and scans must be done within 4 weeks prior to registration.

12. Patients classified to have mild-moderate abnormalities in any of the domains evaluated in the screening geriatric assessment (as outlined in the table in Section 10.1) and are classified as "vulnerable" are eligible.
    Patients classified without any abnormalities ("fit") or with severe cognitive/functional impairment or high co-morbidity score ("frail") on the screening geriatric assessment are ineligible.

13. Patient must agree not to take any medications or substances that are strong inhibitors or inducers of CYP3A4. Those who are randomized to liposomal irinotecan treatment arm should avoid drugs that are UGT1A1 inhibitors.

**Schema**




1. Patients will complete a comprehensive geriatric assessment and Quality of Life prior to starting treatment.