

FAST FACTS

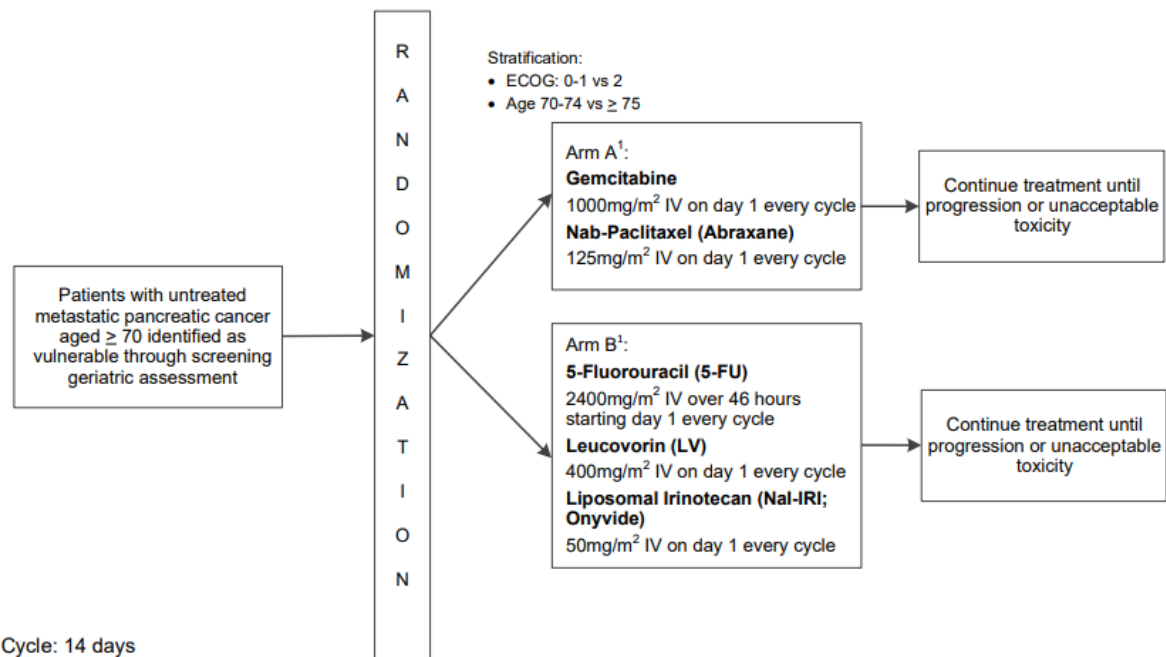
EA2186 - A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)

Eligibility Criteria

1. Patient must have newly diagnosed untreated biopsy proven metastatic adenocarcinoma of the pancreas. If a patient had a biopsy of the pancreatic mass and the clinical picture is consistent with metastatic pancreatic cancer, another biopsy of a metastatic site is not required for this trial. Patients with acinar cell or adenosquamous carcinoma histology are ineligible. Patients with neuroendocrine histology are ineligible.
2. Patients who have had previous surgery, adjuvant/neoadjuvant chemotherapy and/or radiation therapy will be allowed to enroll, provided therapy was completed at least 6 months prior to randomization. Palliative radiation to a metastatic site prior to study enrollment is allowed.
3. Patient must be ≥ 70 years of age.
4. Patient must have an ECOG Performance status 0-2
5. Patient must be an English speaker with the ability to understand and complete the informed consent and questionnaires
6. Patient must have adequate organ and marrow function as defined below, with results obtained within 4 weeks prior to randomization:
 - a. Leukocytes $\geq 3,000/\text{mcL}$
 - b. Absolute neutrophil count (ANC) $\geq 1,500/\text{mcL}$
 - c. Platelets $\geq 100,000/\text{mcL}$
 - d. Total bilirubin \leq institutional upper limit of normal (ULN)
 - e. AST(SGOT)/ALT(SGPT) $\leq 2.5 \times$ institutional ULN
 - f. Creatinine \leq institutional ULN OR glomerular filtration rate (GFR) $\geq 40 \text{ mL/min/1.73 m}^2$
7. Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of randomization are eligible for this protocol. HIV (+) patients who are on ritonavir or/and cobicistat-based regimen must be switched to alternative ART.
8. For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated.
9. 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.
10. Patients must agree not to father children while on study and for 3 months after the last dose of protocol treatment.

11. 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 2 or better.
12. Patient must have measurable disease as defined in Section 6.1.2 and scans must be done within 4 weeks prior to randomization.
13. 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.
14. Patient should avoid taking 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.