Now Enrolling: GIANT (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)

Currently, there is no established standard of care for older adults with metastatic pancreatic cancer – yet over 65% of new pancreatic cancers are discovered in people aged 65 and over. The GIANT study, led by Dr. Efrat Dotan (Fox Chase Cancer Center), aims to obtain much needed data to guide oncologists regarding the optimal management of patients over the age of 70 with newly diagnosed metastatic pancreatic cancer. GIANT is the first prospective randomized study in this patient population.

Participants will be randomized to one of two treatment regimens: gemcitabine and nab-paclitaxel given every other week or dose-reduced 5-fluorouracil and liposomal irinotecan given every other week. The study team selected these therapies based on common oncologic practice in the management of older patients with metastatic pancreatic cancer. The primary endpoint of the trial is overall survival.

Ultimately, GIANT will provide important prospective data regarding the ability of older patients to tolerate treatment and the efficacy of these treatments in older adults. Furthermore, the novel design using a screening geriatric assessment for patient selection (available on the CTSU website on the EA2186 protocol page under “Documents” > “Education and Promotion”) will help to clearly define the patient population that should receive such treatment. It is hoped that GIANT will identify the recommended treatment regimen for older adults and a regimen that can be used in the future as a base to study novel treatment options in these patients.

Learn more about GIANT on ECOG-ACRIN.org.