EA2192/APOLLO

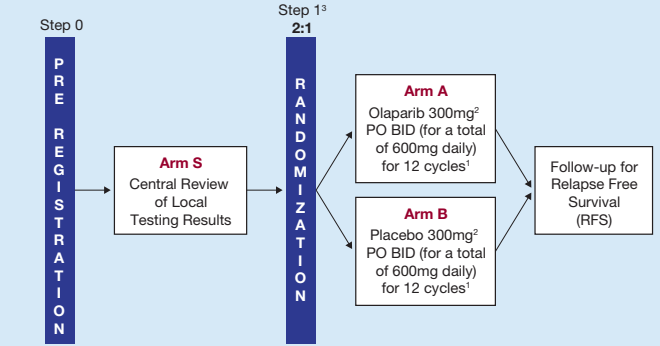
Randomized Phase II Double-Blind Study of Olaparib versus Placebo following Curative Intent Therapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2, or PALB2 Mutation

Overall EA2192 Study Objective

To investigate how well the addition of olaparib following conventional therapy works in treating patients with pancreatic cancer that has been surgically resected and has a pathogenic BRCA1, BRCA2, or PALB2 mutation

- Olaparib is an inhibitor of the PARP enzyme, which is responsible for repairing DNA when it becomes damaged
- Blocking PARP may help keep tumor cells from repairing their damaged DNA, causing them to die

Study Schema



Accrual = 152

[1]One cycle = 4 weeks

[2]Olaparib is supplied in either 100mg or 150mg tablets

[3]Patients will be randomized in a **2:1** fashion. For every two patients who receive olaparib, one patient will receive placebo

Note: When a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm X. The patient will actually be randomized to Arm A or B, but as this is a double-blind trial, that information cannot be displayed.

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Study Objectives

Primary Study Objective

- Improvement in relapse-free survival (RFS)
  - From randomization to disease recurrence or death, from 22 months to 44 months

Secondary Objectives

- RFS from randomization to disease recurrence or death up to 5 years
- Overall survival (OS) from randomization until 10 years or until death
- Efficacy of olaparib after chemotherapy in patents with germline vs somatic mutations
- Differences in survival up to 10 years in patients who received neoadjuvant chemotherapy versus adjuvant chemotherapy alone
- Several additional exploratory analyses of biomarkers and RFS/OS comparing subgroups of patients receiving perioperative platinum-based chemotherapy

Eligibility Criteria*

Main Inclusion Criteria

- Age ≥18 years
- ECOG performance status of 0–2
- Diagnosis of pancreatic cancer (adenocarcinoma, acinar carcinoma, and squamous cell carcinoma are allowed)
- Curative intent surgical resection with no evidence of disease
- At least 3 combined months of systemic, multi-agent chemotherapy
- Patients must be within 12 weeks of the most recent intervention (surgery, chemotherapy, or radiation)
- Pathogenic BRCA1, BRCA2, or PALB2 mutation

Main Exclusion Criteria

- Recurrent or metastatic pancreatic cancer
- Neuroendocrine tumor
- Progression of disease while receiving platinum-based chemotherapy
- Receiving any other investigational agent at randomization

*When evaluating patients for this study, please refer to the full protocol for the complete list of eligibility criteria.

EA2192 Pocket Reference Card v.10/02/23

NCI National Clinical Trials Network

ECOG-ACRIN cancer research group