NCI National Clinical Trials Network

EA2234/STOPGAP II

For Patients with Gastric Carcinomatosis

Please Enroll Your Eligible Patients!

EA2234 Available Through ECOG-ACRIN Cancer Research Group

A Randomized Phase II/III Trial of Intraperitoneal Paclitaxel plus Systemic Treatment vs Systemic Treatment Alone in Gastric Carcinomatosis – STOPGAP II

Patient Population

See protocol Section 3 for complete eligibility criteria

Step 0 Registration Eligibility Criteria:

- At least 18 years old, ECOG PS 0-1, adequate lab values
- Histologically or cytologically confirmed MSS or MMR protein expression proficient primary gastric or gastroesophageal adenocarcinoma (Siewert 3) with synchronous cytology positive disease (cyt+), ***OR*** peritoneal carcinomatosis detected by imaging, laparoscopy, or laparotomy (Note: patients with MSI-H/ dMMR are not eligible)
- Received a minimum of 3 months/maximum of 6 months first line systemic treatment; registered to Step 0 within ≤ 4 weeks of last dose of first line systemic therapy
  - ◊ No ongoing significant AEs that would prohibit a diagnostic laparoscopy procedure followed by further systemic and intraperitoneal therapy
- Must have no evidence of the following:
  - ◊ Small or large bowel obstruction (other than gastric outlet obstruction due to primary malignancy)
  - ◊ Solid organ metastases (except ovarian)
  - ◊ Clinically significant radiologic peritoneal disease progression during first line systemic therapy
  - ◊ Extensive retroperitoneal lymph node metastases not amenable to resection during gastrectomy
  - ◊ Massive ascites on imaging or history of 2 therapeutic paracentesis with drainage of > 1.0 liter of ascites each time ≤ 30 days of Step 0 registration
- No history of prior surgery that would preclude safe diagnostic laparoscopy and port placement
- Patients should be NYHA class II or better, if applicable

Step 1 Randomization Eligibility Criteria:

- Must have undergone diagnostic laparoscopy; peritoneal lavage performed and aspiration for cytology obtained
- Peritoneal disease burden assessed during diagnostic laparoscopy with PCI available (see Appendix V)
- No extensive intraabdominal adhesions that preclude safe placement of intraperitoneal port

Treatment Plan

See protocol Section 5 for complete treatment details

Patients are randomized during the diagnostic laparoscopy. Patients on Arm A do not require port placement; patients on Arm B will undergo insertion of the intraperitoneal port at the time of diagnostic laparoscopy. Treatment must start 1-30 calendar days after randomization

Arm A: Systemic Therapy:

- Physician's choice of any SOC systemic regimen for gastric/GEJ adenocarcinoma, including local institutional regimens and targeted agents
- For Arm A, chemo may be administered at a non-enrolling/non-registering site (see Section 5.1.1)

Arm B: Systemic Therapy + Intraperitoneal Paclitaxel:

- Premedications per protocol
- Administer therapy on Days 1 and 8 of 21-day cycles, for up to 4 cycles, in the following sequence:
  - ◊ Leucovorin 20 mg/m² IV
  - ◊ 5-FU 400 mg/m² IV push
  - ◊ Paclitaxel 50 mg/m² IV
  - ◊ Paclitaxel 40 mg/m² IP

Both Arms:

- May continue simultaneous treatment with FDA-approved immune checkpoint inhibitors, targeted therapies, or biosimilars (investigational agents not permitted) as appropriate
- 12 weeks (+/- 2 weeks) after start of treatment, obtain restaging imaging (CT and/or diffusion weighted MRI with contrast); if responding or stable disease, continue assigned treatment and restage every 12 weeks (+/- 2 weeks)
- Treatment will continue until clinical or radiographic progression, unacceptable toxicity, or cytoreduction
- Cytoreduction may be offered if no clinical or radiographic progression, PCI < 7, and complete cytoreduction feasible per treating surgeon; perform within 6 weeks of last study treatment (see Section 5.2)

Study Chair:
Maheswari Senthil, MD, FACS, FSSO

Study Co-Chair:
Nataliya V. Uboha, MD, PhD

NCTN Study Champions:
- ***Alliance:*** Mehraneh Dorna Jafari, MD, FACS, FASCRS
- ***NRG:*** Ibrahim Nassour, MD
- ***SWOG:*** Divya Sood, MD

Patient Enrollment (Oncology Patient Enrollment Network [OPEN])

https://open.ctsu.org/open 1-888-823-5923

Protocol Information (ECOG-ACRIN Operations – Boston)

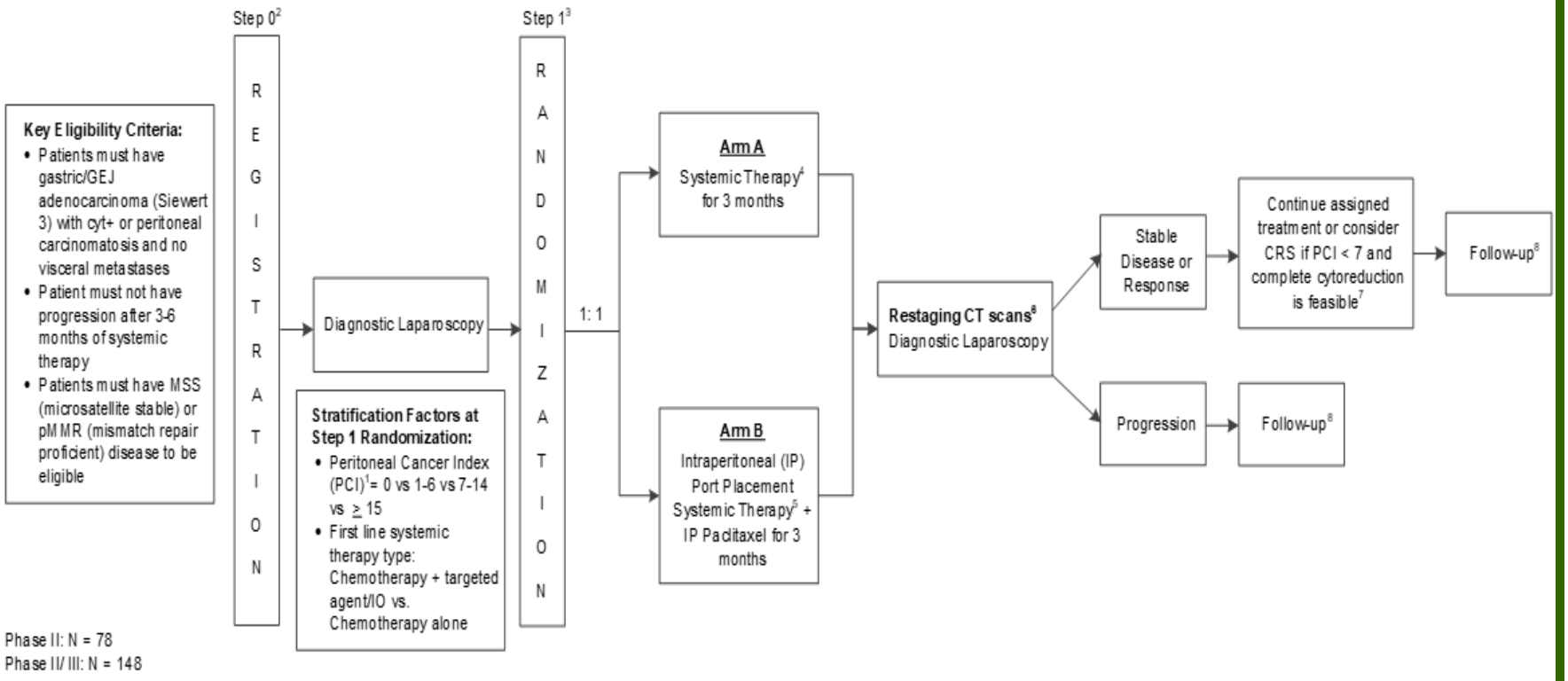
http://ecog-acrin.org (Member Login) 1-857-504-2900

v.07/09/26 (Add. #2)

ECOG-ACRIN cancer research group

EA2234

Schema



1. See Appendix V for the PCI Calculator.
2. Step 0 is where patients will be fully consented and eligibility confirmed. Patients must by registered to Step 0 within 4 weeks after the last dose of first line therapy. The diagnostic laparoscopy must be planned and scheduled within 4 weeks of Step 0 registration
3. Patient are randomized 1:1. All patients will be randomized **in the operating room** after the PCI score has been calculated by the surgeon. All sites must be prepared for the intraoperative randomization process by ensuring all of the procedures outlined in Section 4.2.6 and Appendix VI are in place ahead of time. Patients who are randomized to Arm B will then undergo insertion of the intraperitoneal port at the time of diagnostic laparoscopy. EA2234 protocol treatment to start within 4 weeks of Step 1 randomization.
4. Arm A patients will receive any standard of care systemic therapy. Patient may also receive targeted therapies/immunotherapy. See Section 5.1.1 for additional details.
5. Arm B patients will receive systemic therapy consisting of 5-FU, Leucovorin and IV Paclitaxel in addition to IP Paclitaxel. Patient may also receive targeted therapies/immunotherapy. See Section 5.1.2 for additional details.
6. Restaging scans with CT and/or diffusion weighted MRI with contrast will be completed after 12 weeks (+/- 2 weeks) of protocol therapy and will continue to be obtained every 4 cycles thereafter. Diagnostic laparoscopy may be considered for surgical decision making at this time.
7. Patients will continue treatment until progression, intolerance/unacceptable toxicity, or cytoreduction.
8. See Sections 5.7 and 7.1 for additional details on follow up.