

NCI

National
Clinical
Trials
Network

EA2234/STOPGAP II

For Patients with Gastric Carcinomatosis

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 I 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

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,
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Study Co-Chair:

Nataliya V. Uboha, MD,
PhD

NCTN Study Champions:

- **Alliance:** Mehraneh Dorna Jafari, MD, FACS, FASCRS
- **NRG:** Ibrahim Nassour, 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

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