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NCI National Clinical Trials Network

EA2183

ECOG-ACRIN cancer research group
Reshaping the future of patient care

For Patients with Oligometastatic HER2– EGA

EA2183 Available Through ECOG-ACRIN Cancer Research Group

A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)

Patient Population

See Section 3.0 for Complete Eligibility Details

Registration to Step 1:

- ≥ 18 years of age, ECOG PS 0-1, and adequate lab values
- Must have histologically confirmed HER2– metastatic esophageal/gastric adenocarcinoma (AJCC 8th ed.)
- Must have oligometastatic disease (see protocol):
  - ◊ At most 3 radiologically visible metastatic lesions (not sites), in addition to the primary site
  - ◊ Anatomically defined lymphadenopathy will be considered as 1 site of metastatic disease
  - ◊ No patients with radiologically evident peritoneal metastasis
- No contraindications to 5-FU/capecitabine/oxaliplatin, or radiation therapy (consultation with radiation oncologist)
- HIV-infected patients must meet criteria per protocol
- Patients with a prior/concurrent malignancy whose natural history/treatment does not have the potential to interfere with the safety/efficacy of the investigational regimen are eligible
- Patients who had prior definitive treatment for early stage EGA with surgery/chemoradiation are eligible as long as recurrent disease developed at least 6 months after prior therapy completion
- No prior treatment with 5-FU/capecitabine/oxaliplatin containing systemic therapy (exceptions per protocol)
- Major surgery must be completed ≥ 4 weeks of registration; no live vaccines within 30 days of registration
- No patients with CNS metastasis; no uncontrolled intercurrent illness (see protocol)

Registration to Step 2:

- Must have histologically confirmed HER2- metastatic esophageal/gastric adenocarcinoma (AJCC 8th ed.) with stable disease after 4 cycles of FOLFOX or 6 cycles of CAPOX (Step 1 treatment)
- Must have no evidence of disease progression (RECIST) since Step 1 registration; patients with complete radiologic response are eligible for Step 2

Treatment Plan

See Section 5.0 for Complete Treatment Details

Step 1– Induction Chemotherapy (2 chemotherapy backbones allowed at the preference of the treating physician):

- **Arm A– FOLFOX:**
  - ◊ 4 cycles of FOLFOX (8 doses); administered days 1 and 15 of each 28 day cycle
  - ◊ Oxaliplatin 85 mg/m² IV and Leucovorin 200 mg/m², followed by 5-FU bolus 400 mg/m², then continuous 5-FU IV over 46-28 hours on days 1 and 15 for a total of 2400 mg/m²
- **Arm B– CAPOX:**
  - ◊ 6 cycles given (each cycle is 21 days)
  - ◊ Oxaliplatin 130 mg/m² IV on day 1; Capecitabine 1000 mg/m² orally days 1-14

Step 2:

- **Arm C– Consolidative RT > FOLFOX:**
  - ◊ Radiotherapy for up to 15 days followed by FOLFOX (per Arm A); 1 week break between completion of chemo in Step 1 and radiotherapy; FOLFOX 2-4 weeks post radiotherapy completion
- **Arm D– FOLFOX Only:** Continue FOLFOX (per Arm A) until disease progression/intolerable toxicity
- **Arm E– Consolidative RT > CAPOX:**
  - ◊ Radiotherapy for up to 15 days followed by CAPOX regimen (Arm B); 1 week break between completion of chemo in Step 1 and radiotherapy; CAPOX 2-4 weeks post radiotherapy completion
- **Arm F– CAPOX Only:** Continue CAPOX (per Arm B) until disease progression/intolerable toxicity

Radiation Therapy:

- Administered using external beam photon RT, with 3D-CRT, IMRT, SBRT, or SRS per treating radiation oncologist (dose/fractionation per treating radiation oncologist as well)

Study Chair:
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Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN), https://open.ctsu.org

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

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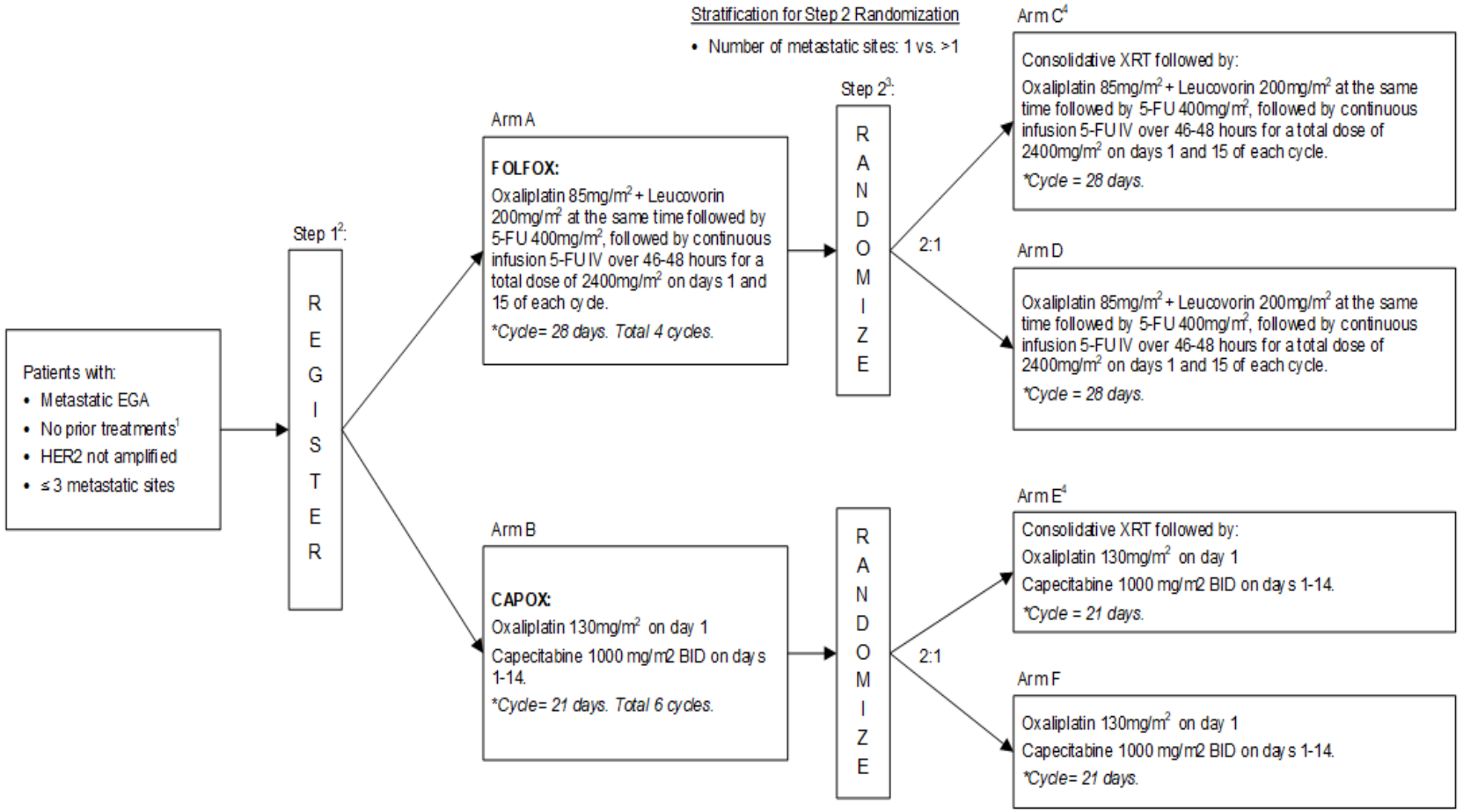
Schema



Accrual: Step 1 = 314, Step 2 = 204

1. No prior systemic treatments for metastatic disease.
2. Treating physician will decide whether to place the patient on Arm A (FOLFOX) or Arm B (CAPOX).
3. Subjects with progressive disease during Step 1 will not be randomized and will be removed from the study.
4. Patients are required to have at least a 1 week break between the last dose of chemotherapy and the first day of radiation to prevent increased toxicities.