

NSABP R-04

For Patients with Operable Carcinoma of the Rectum

NSABP-R-04 Available Through the CTSU

A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum

Patient Population

See Protocol Section 5.0 for Full Eligibility Details

- Patients must have a diagnosis of rectal adenocarcinoma obtained by biopsy such that a major portion of tumor remains intact.
- There must be no more than 42 days between initial diagnosis and randomization.
- Tumor must be clinically stage II or III.
- Tumor must be either palpable by DRE or accessible via a proctoscope or sigmoidoscope, and its distal border must be located < 12 cm from the anal verge.
- Tumor must be considered by a surgeon to be amenable to curative resection.
- No findings of metastatic disease.
- No prior invasive rectal cancer.
- No synchronous colon cancer.
- No previous treatment for the current rectal cancer or prior pelvic radiation for any reason.
- No class III or IV myocardial disease, recent MI, symptomatic arrhythmia, uncontrolled HTN or coagulopathy, active IBD, or clinically significant peripheral neuropathy.
- Zubrod performance status 0 or I
- **Number of Patients: 1606**

Treatment Plan

See Protocol Section 9.0 for Full Treatment Regimen Directions

Group 1: RT with 5-FU

- RT*
- 5-FU 225mg/m²/day CIVI 24hrs/day 5 days/week on days of planned RT

Group 2: RT with 5-FU + Oxaliplatin

- RT*
- Oxaliplatin 50mg/m² IV q week x 5
- 5-FU 225mg/m²/day CIVI 24hrs/day 5 days/week on days of planned RT

Group 3: RT with Capecitabine

- RT*
- Capecitabine 825mg/m² BID 5 days/week on days of planned RT

Group 4: RT with Capecitabine + Oxaliplatin

- RT*
- Oxaliplatin 50mg/m² IV q week x 5
- Capecitabine 825mg/m² BID 5 days/week on days of planned RT

All patients proceed to surgery. It is then recommended that they receive adjuvant therapy. Please consider enrolling R-04 patients onto ECOG E5204.

*RT– 180 cGY/day x 25 fractions, followed by tumor boost of 180 cGY/day x 3 fractions (T3 tumors) or x 6 fractions (T4 and distal tumors)

Patient Enrollment

Non-NSABP Members: CTSU Patient Registrar 1-888-462-3009

Protocol Information

CTSU Help Desk: 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

NSABP
Protocol Chair:
Robert W. Beart, Jr., MD

CALGB
Co-Chair:
David Ryan, MD

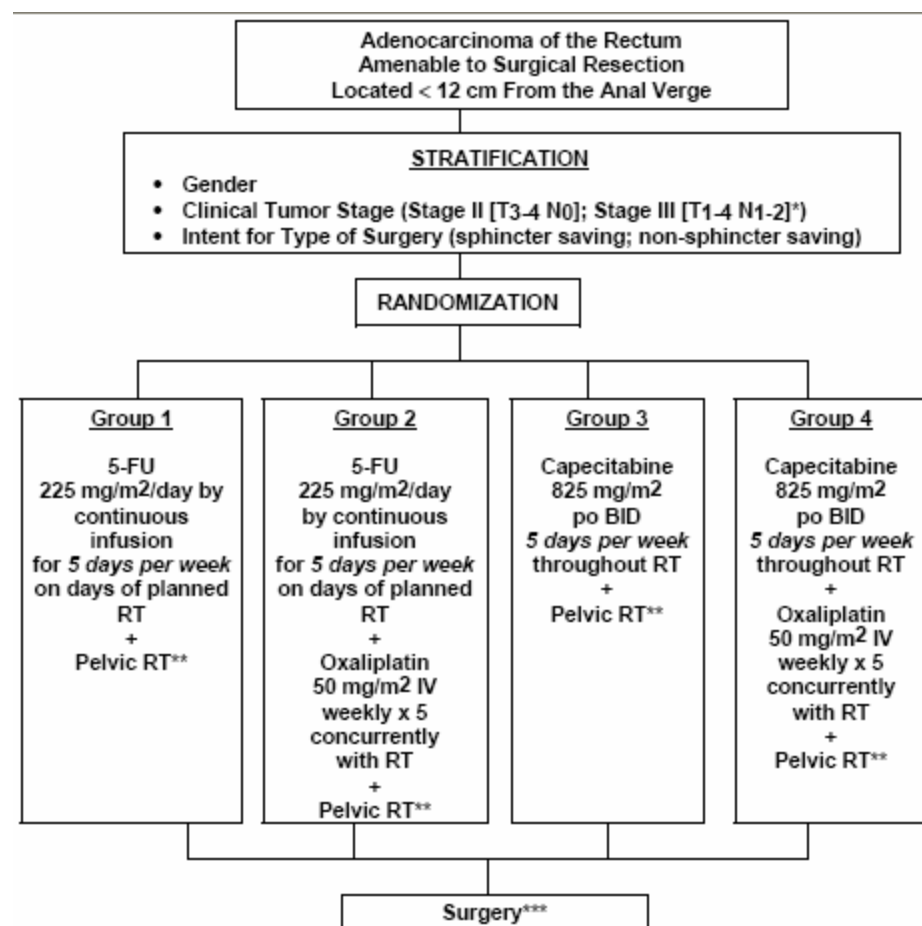
NCCTG
Co-Chair:
Henry Pitot, MD

SWOG
Co-Chair:
Anthony Shields, MD

Schema

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* Definition of a clinically positive node is any node ≥ 1.0 cm.

** 4,500 cGy in 25 fractions over 5 weeks + 540 cGy boost for non-fixed tumors (3 fractions) or 1,080 cGy boost for fixed tumors (6 fractions).

*** Following surgery, patients should be strongly encouraged to receive adjuvant therapy. Investigators should consider enrolling R-04 patients in ECOG E5204.