

PROTOCOL CARD, ECOG 5204

Rectal Cancer Protocol Version 8/24/06

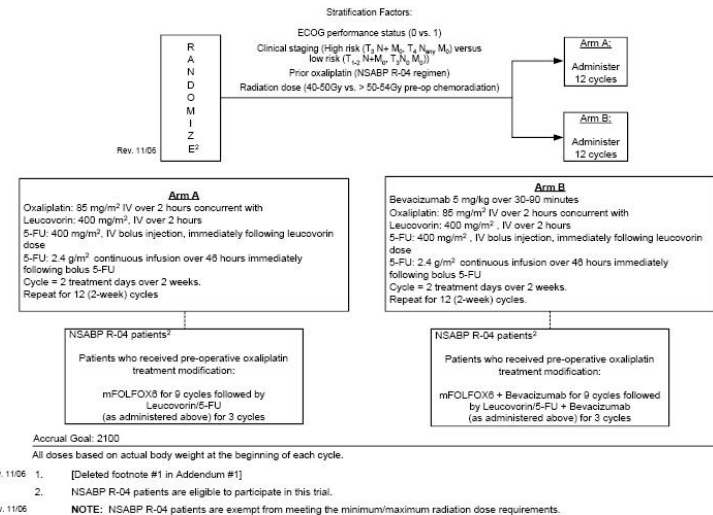
Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Pre-operative Chemoradiation.

Eligibility

- Patients must have histologically-proven adenocarcinoma of the rectum with no distant metastases. Clinical (prior to neoadjuvant therapy) and pathologic staging are required.
- Patients must have clinical stage T₃N₀M₀, T₄N₀M₀, or T_{any}N₁₋₂M₀.
- Patients must have no evidence of tumor outside the pelvis including liver metastases, peritoneal seeding, or metastatic inguinal lymphadenopathy. Lack of metastatic disease must be confirmed by imaging.
- Patients must have received a minimum radiation dose of 40 Gy and not more than 54 Gy. Prior IMRT is not allowed. Patients who participate in R-04 are exempt from meeting min/max RT dose requirements.
- Patients that did not participate in NSABP R-04 must have received a) XRT + CIVI 5-FU or b) XRT + 5-FU/LV.
- Patients that did participate in NSABP R-04 must have received a) XRT + capecitabine ± oxaliplatin or b) XRT + CIVI 5-FU ± oxaliplatin.
- Patients must have a completely resected tumor and be between 28-56 days from the date of surgery.
- Rectal location of the tumor must be confirmed either prior to neoadjuvant therapy or at the time of surgery; either a) the distal border was measured as < 12 cm from the anal verge or b) during surgery, a portion of the tumor was identified below the peritoneal reflection.
- Transmural penetration of tumor through the muscularis propria or regional LN involvement must be confirmed via CT, MRI, or endorectal US prior to neoadjuvant therapy.
- The tumor may be clinically fixed or initially not completely resectable, clinical stage T₄N₀₋₂M₀, based on criteria outlined in Section 3.1.1.
- Patients must be ≥ 18 years of age; ECOG PS 0-1.
- Patients must not have received prior chemotherapy or pelvic radiation except as neoadjuvant treatment for current diagnosis as already described.
- Patients must not have a previous or concurrent malignancy except for nonmelanoma skin cancer or CIS of the cervix, or any treated non-pelvic cancer from which the patient has been continuously disease-free for more than 5 years.
- Patients must not have active IBD or other serious medical illness which might limit the ability of the patient to receive protocol therapy.
- Females must not be pregnant or breast-feeding. All patients (when appropriate) must be willing to use an effective form of contraception during study therapy and for at least 3 months after the completion of bevacizumab.
- Patients must not have history of arterial thrombotic events, unstable angina, or MI within 12 months of study entry; active gastroduodenal ulcers; serious or non-healing wound, skin ulcers or bone fracture; Class III or IV cardiac disease; current symptomatic arrhythmia; history of TIA or CVA; significant PVD; or ≥ grade 2 peripheral neuropathy.
- Patients must not have significant bleeding not related to the primary rectal tumor within 6 months of study entry.
- Patients must not be receiving concomitant halogenated antiviral agents.
- Patients with history of HTN must have BP of <150/90 and be on stable regimen of anti-hypertensives.

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- Patients must not have psychiatric or addictive disorders or other conditions that would preclude them from meeting study requirements.
- Patients must not have had a) major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to randomization, b) core biopsy or other minor procedure within 7 days prior to randomization, or c) anticipate the need for major surgical procedure during the course of the study.



Required Laboratory / Tests

(Bloodwork within 2 weeks prior to randomization)

- AGC ≥ 1,500/mm³
- Platelets ≥ 100,000/mm³
- Bilirubin ≤ ULN (unless Gilbert's or similar condition)
- Alkaline phosphatase < 2.5 x ULN
- AST < 1.5 x ULN
- Hep B and C testing only if AST > ULN
- Serum Creatinine < 1.5 x ULN
- UPC ratio < 1.0 or see Section 3.31
- PT (INR) ≤ 1.5 or see Section 3.32
- Pregnancy Test when applicable
- CEA level
- CT, Transrectal MRI or U/S
- Colonoscopy or barium enema
- Image of Chest (CXR or CT)
- Image of Liver (CT or MRI)

THIS INFORMATION IS INTENDED TO BE USED AS A SCREENING TOOL ONLY AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL.