Testing the Addition of an Anti-Cancer Drug, Irinotecan, to the Standard Chemotherapy Treatment (FOLFOX) After Long-Course Radiation Therapy for Advanced-Stage Rectal Cancers to Improve the Rate of Complete Response and Long-Term Rates of Organ Preservation

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Stage: Clinical stage II or III rectal adenocarcinoma defined as T4N0 or any T with node positive disease (any T, N+); also T3N0 requiring abdominal perineal resection (APR) or coloanal anastomosis * Tumor site: Rectum; =\< 12cm from the anal verge * No prior systemic chemotherapy, targeted therapy, or immunotherapy; or radiation therapy administered as treatment for colorectal cancer within the past 5 years is allowed * Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects * Therefore, for women of childbearing potential only, a negative pregnancy test (urine or serum according to institutional guidelines) done =\< 14 days prior to registration is required. Female subjects agree to use highly effective contraception combined with an additional barrier method (e.g, diaphragm, with a spermicide) while on study and for \>= 9 months after last dose of study drug, and the same criteria are applicable to male subjects if they have a partner of childbirth potential. Male subject agrees to use a condom and not donate sperm while in this study and for \>= 6 months after the last treatment * Age \>= 18 years * Eastern Cooperative Oncology Group (ECOG) performance status =\< 2 (or Karnofsky \>= 60%) * Absolute neutrophil count (ANC) \>= 1,500/mm\^3 * Platelet count \>= 100,000/mm * Creatinine =\< 1.5 x upper limit of normal (ULN) OR calculated (calc.) creatinine clearance \>= 50 mL/min \^3 * Total bilirubin =\< 1.5 x upper limit of normal (ULN) * Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) =\< 3 x upper limit of normal (ULN) * No upper rectal tumors (distal margin of tumor \> 12 cm from the anal verge) * No recurrent rectal cancer; prior transanal excision, prior distal sigmoid cancer with a low anastomosis * No known mismatch repair deficient rectal adenocarcinoma * Human immunodeficiency virus HIV-infected patients on effective anti-retro viral therapy with undetectable viral load within 6 months are eligible for this trial * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardio toxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification1. To be eligible for this trial, patients should be class 2B or better * Chronic concomitant treatment with strong inhibitors of CYP3A4 is not allowed on this study. Patients on strong CYP3A4 inhibitors must discontinue the drug for 14 days prior to registration on the study * Chronic concomitant treatment with strong CYP3A4 inducers is not allowed. Patients must discontinue the drug 14 days prior to the start of study treatment

Conditions & Interventions

Interventions:
DRUG: Capecitabine, DRUG: 5-fluorouracil, DRUG: Leucovorin calcium, DRUG: Irinotecan, DRUG: Oxaliplatin, RADIATION: Long Course Chemoradiotherapy, PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Sigmoidoscopy, PROCEDURE: biopsy
Conditions:
Locally Advanced Rectal Carcinoma, Stage II Rectal Cancer AJCC v8, Stage III Rectal Cancer AJCC v8

More Information

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