Total Neoadjuvant Therapy With mFOLFOX and Short-course Radiation in Resectable Rectal Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Pathologic diagnosis of adenocarcinoma of the rectum (diagnosis by tissue biopsy) within 90 days prior to registration. At least a portion of the tumor must be located below the peritoneal reflection or begin within 12 cm of the anal verge on flexible endoscopy * Clinically staged (AJCC 8th ed.) T3-4 N0 M0 or T any N1-2 M0 based upon the following minimum diagnostic workup: * Colonoscopy, unless patient presents with an obstructing lesion * Within 30 days prior to registration: * History/physical examination * Imaging to exclude distant metastases: either contrast-enhanced CT of the chest, abdomen, and pelvis or whole-body PET-CT or MRI * Pelvic MRI (preferred) or transrectal ultrasound (TRUS) for T staging * ECOG Performance Status ≤1 * Age ≥ 18 years * Adequate bone marrow function defined as follows: * Absolute neutrophil count (ANC) ≥ 1,200 cells/mm3 * Platelets ≥ 100,000 cells/mm3 * Hemoglobin ≥ 8.0 g/dL (Note: The use of transfusion or other intervention to achieve Hgb ≥8.0 g/dL is acceptable.) * Adequate liver and renal function defined as follows: * AST and alkaline phosphatase \< 2.5 x upper limit of normal (ULN) * Bilirubin ≤ 2.5 ULN * Calculated creatinine clearance (CrCl) \> 30 mL/min using Cockcroft-Gault formula as calculated by the standard Cockcroft-Gault equation using age, actual weight, creatinine, and gender * Must be deemed a candidate for curative resection by the surgical oncologist who will be performing the operation * Women of childbearing potential (WCBP) must have a negative serum pregnancy test performed within 7 days prior to the start of chemotherapy. * WCBP and men must agree to use a medically accepted form of birth control during the treatment and for 3 months following completion of chemotherapy. * Ability to understand and the willingness to sign a written informed consent document.

Exclusion Criteria:

* Prior RT that would result in overlap of RT fields with the planned study treatment * Clinically significant cardiac disease, including major cardiac dysfunction, that in the opinion of the treating medical oncologist would preclude them from receiving systemic therapy with 5-fluorouracil, leucovorin or oxaliplatin. * Serious (ie, ≥ grade 3) uncontrolled infection * Pulmonary or respiratory condition that, in the opinion of the treating medical oncologist would preclude them from receiving systemic therapy with 5-fluorouracil, leucovorin or oxaliplatin. * Major surgery within 28 days of study enrollment (other than diverting colostomy) * History of inflammatory bowel disease (eg, Crohn's disease, ulcerative colitis) requiring significant intervention (eg, hospitalization, surgery, immunosuppressive medications) that would, in the opinion of the investigator, preclude study therapy * Prior known allergic reaction to 5-fluorouracil, leucovorin, or oxaliplatin * Known dipyrimidine dehydrogenase deficiency (DPD) * Any evidence of distant metastases (M1) * Pregnant or breast feeding * Medical, psychological, or social condition that, in the opinion of the investigator, may increase the patient's risk or limit the patient's adherence with study requirements

Conditions & Interventions

Interventions:
DRUG: Chemotherapy, RADIATION: Radiation Therapy
Conditions:
Rectal Cancer
Keywords:
Resectable, Rectal

More Information

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