Addition of Antibiotics to Upfront Treatment Regimen for Colorectal Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Diagnosis of stage IV colorectal cancer * Measurable disease by Response evaluation criteria in solid tumors (RECIST) 1.1 criteria * Planned first-line treatment with a 5FU-based doublet chemotherapy regimen for colon cancer, specifics of the regimen at the discretion of the treating physician Note: Patients who have received adjuvant therapy \>6 months prior are eligible * Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0-2 * Absolute neutrophil count (ANC) ≥1,500 cells/µL * Platelet count ≥100,000 cells/µL * Hemoglobin ≥8 g/dL Note: The use of transfusion or other intervention to achieve hemoglobin ≥8 g/dL is acceptable. * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤2.5 × upper limit of normal (ULN) Note: Patients with documented liver metastases: AST and ALT ≤5 × ULN * Serum creatinine ≤1.5 x ULN or calculated creatinine clearance ≥40 mL/min using the Cockcroft-Gault equation: (140

•age) × body weight/plasma creatinine × 72 (× 0.85 if female) * Radiographically measurable disease by RECIST 1.1 * Nonpregnant and not actively breastfeeding * Sexually active patients of childbearing potential and their partners must agree to use medically acceptable form of contraception, per treating investigator, throughout the study Patients should continue to use medically acceptable methods of contraception after study treatment ends, following the guidance for their specific chemotherapy regimen. Childbearing potential excludes: Age \> 50 years and naturally amenorrhoeic for \> 1 year OR previous hysterectomy or bilateral salpingo-oophorectomy

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Exclusion Criteria:

* ongoing full dose anticoagulation Note: Patients on full dose anticoagulation may be approached to discuss study participation if lowering anticoagulation dose is feasible per the discretion of the treating investigator. Patients will be required to lower the anticoagulation dose by half 48 hours before beginning study drugs * Total colectomy * Diagnosed with Cockayne Syndrome * Using disulfiram, tizanidine, or theophylline and unable to stop taking these medications for the length of the microbiome modulation therapy * On methotrexate doses of 15 mg/week or more * History of allergic reaction to ciprofloxacin, metronidazole, or aspirin * Antibiotic use in the 30 days before chemotherapy start Note: Use of antibiotics intended for prophylaxis at the time of surgery is allowed * Corrected QT interval (QTc) \>480 on baseline ECG * Clinically significant hematuria, hematemesis, or hemoptysis of \>0.5 teaspoon (2.5 mL) of red blood, or other history of significant bleeding (eg, pulmonary hemorrhage) within 12 weeks before first dose of microbiome modulation therapy (significance determined by treating investigator) * Diagnosed with a malabsorptive syndrome * Inability to swallow tablets

Conditions & Interventions

Interventions:
DRUG: Standard of Care Chemotherapy + Metronidazole, ciprofloxacin, aspirin
Conditions:
Colorectal Cancer, CRC
Keywords:
Colorectal Cancer, CRC

More Information

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