Studying the PAGODA Algorithm for Chemotherapy Dose Changes to Prevent Unplanned Treatment Delays

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* * REGISTRATION ELIGIBILITY CRITERIA (STEP 1) * Histologic confirmation of invasive cancer that is confirmed or suspected to arise from the gastrointestinal (GI) tract * Any stage for which FOLFOX-based chemotherapy is a clinically-indicated, standard-of-care treatment (adjuvant, neoadjuvant, or first-line chemotherapy) * Eligible primary tumor sites include the esophagus, gastroesophageal junction, stomach, small intestine, ampulla of Vater, appendix, colon, rectum, and cancers of unknown primary with suspected GI origin * Prior systemic therapy for GI cancer (other than cycle 1 of FOLFOX-based chemotherapy) is not allowed. Prior radiation-sensitizing chemotherapy is permitted * The planned duration of FOLFOX-based chemotherapy must be at least four cycles (1 cycle = 14 days) * Cycle 1, day 1 of FOLFOX-based chemotherapy must be completed 1 to 8 days prior to registration * Cycle 1, day 1 of FOLFOX-based chemotherapy must include minimum ordered doses of oxaliplatin (≥ 65 mg/m\^2) and infusional 5-FU (2400 mg/m\^2/46 hours). Use of the 5-FU bolus is at the discretion of the treating physician * Patients who require primary prophylactic white blood cell growth factor with cycle 1 of FOLFOX chemotherapy due to high risk for fever and neutropenia are not eligible * History of hypersensitivity reaction to oxaliplatin or other platinum-based drugs, to fluorouracil, or to leucovorin, and the excipients in their formulations are not eligible * Age ≥ 18 years * ECOG performance status ≤ 2 * Absolute neutrophil count (ANC) ≥ 1,000/mm\^3 * Platelet count ≥ 100,000/mm\^3 * Total bilirubin ≤ 3 x upper limit of normal (ULN) * AST (SGOT)/ALT (SGPT) ≤ 5 x upper limit of normal (ULN) * Calc. creatinine clearance ≥ 30 mL/min * Not pregnant and not nursing, because this study involves agents that have known genotoxic, mutagenic and teratogenic effects. Therefore, for women of childbearing potential only, a negative pregnancy test done ≤ 30 days prior to registration is required * Patients with treated brain metastases are eligible if follow-up brain imaging after CNS-directed therapy shows no evidence of progression * Patients with known HIV infection are eligible if receiving effective anti-retroviral therapy with undetectable viral load within 6 months prior to registration * Patients with known chronic hepatitis B virus (HBV) infection are eligible if HBV DNA is undetectable when measured within 6 months prior to registration * Patients with a known history of hepatitis C virus (HCV) infection are eligible if HCV RNA is undetectable when measured at least 12 weeks after completion of antiviral therapy * Patients with known history or current symptoms of cardiac disease are eligible if the New York Heart Association Functional Classification is class I or II * Patients with a known history of congenital long QT syndrome are ineligible * Patients with known DPD deficiency are ineligible * * NON-PATIENT (ONCOLOGY PHYSICIAN OR ONCOLOGY ADVANCED PRACTICE PROVIDER ELIGIBILITY: * The non-patient provider participant is a medical oncologist or oncology advanced practice provider with responsibility for signing and making necessary modifications to chemotherapy orders for a subject assigned to the intervention arm (Arm B). Non-patient participants may not be enrolled more than once over the course of the study * The non-patient participant must be proficient in the English language * The non-patient participant must be age 21 years or older

Conditions & Interventions

Interventions:

OTHER: PAGODA algorithm, DRUG: Oxaliplatin, DRUG: Folinic Acid, DRUG: Fluorouracil

Conditions:

Ampulla of Vater Carcinoma, Appendix Carcinoma, Carcinoma of Unknown Primary With Gastrointestinal Profile, Colon Carcinoma, Esophageal Carcinoma, Gastric Carcinoma, Gastroesophageal Junction Carcinoma, Malignant Digestive System Neoplasm, Rectal Carcinoma, Small Intestinal Carcinoma

More Information

Contact(s): Lilli Johnson - cancercontrolprotocols@allinancenctn.org

Principal Investigator:

IRB

Number:

System ID: NCT07283939