Testing the Use of Chemotherapy After Surgery for High-Risk Pancreatic Neuroendocrine Tumors

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have a histologic diagnosis of well-differentiated pancreatic neuroendocrine tumor (pNET) that was resected between 14 and 90 days prior to registration. Participants must have a scan within 90 days prior to registration without evidence of metastatic disease. Acceptable scans are multiphase computed tomography (CT) abdomen, magnetic resonance imaging (MRI) with intravenous (IV) contrast of the abdomen, or positron emission tomography (PET)-CT DOTATATE imaging if the DOTATATE PET-CT included IV iodine contrast for the CT portion of the exam * Resection must have been an R0 or R1 per treating investigator's assessment and/or pathology report * Ki-67 testing, which is considered part of standard of care in the pathology report, must have been performed between 14 and 90 days prior to registration and the result must be \>= 3% and =\< 55%. Treating investigators are encouraged to contact the S2104 Study Chairs and/or the study pathology chair with questions. If more than one Ki-67 is reported (e.g., primary tumor versus lymph node or metastatic site), the highest one should be considered for the study eligibility criteria * Participants with localized resected pNETS must have a Zaidi score of \>= 3 derived by the following factors and points: * 1 point; symptomatic tumor defined as one of the following: * Gastrointestinal bleed * Jaundice * Gastrointestinal obstruction * Pain from primary tumor prior to surgical resection * Pancreatitis * 2 points; primary pancreas tumor size \> 2 cm * 1 point; Ki-67 3% to 20% * 1 point; lymph node positivity = 1 * 6 points; Ki-67 21% to 55% * Participants may have received resection/ablation of liver oligo-metastatic disease (up to 5 liver metastases) at the time of well-differentiated pNET resection * Participants must have recovered from effects of surgery as determined by the treating investigator * Participants must be \>= 18 years old * Participants must have Zubrod performance status of 0-2 * Participants must have a complete medical history and physical exam within 28 days prior to registration * Leukocytes \>= 3 x 10\^3/uL (within 28 days prior to registration) * Absolute neutrophil count \>= 1.5 x 10\^3/uL (within 28 days prior to registration) * Platelets \>= 100 x 10\^3/uL (within 28 days prior to registration) * Total bilirubin =\< institutional upper limit of normal (ULN) unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin =\< 5 x institutional ULN (within 28 days prior to registration) * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) =\< 3 x institutional ULN (within 28 days prior to registration) * Serum creatinine =\< 1.5 x institutional ULN (within 28 days prior to registration) * Calculated creatinine clearance \>= 50 ml/min (within 28 days prior to registration) * Participants must be able to swallow pills * Participants must be able to tolerate CT or magnetic resonance (MR) imaging including contrast agents as required for their treatment and the protocol * No other active malignancy or history of prior malignancy is allowed, except for the following: adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated stage I or II cancer from which the participant is currently in complete remission, or any other cancer from which the participant has been disease free for two years * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines

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Exclusion Criteria:

* Participants must not have unresected or unablated metastatic disease * Participants must not have clinically apparent central nervous system metastases or carcinomatous meningitis * Participants must not have received prior neoadjuvant therapy for treatment of pancreatic neuroendocrine tumor. Use of somatostatin analogs prior to surgery is permitted * Participants must not have received somatostatin analogs after surgery * Participants must not be planning to receive warfarin while on protocol treatment. Other anticoagulants are allowed * Participants must not have history of allergic reactions attributed to compounds of similar chemical or biologic composition to temozolomide or capecitabine * Participants must not have known absorption issues that would limit the ability to absorb study agents * Participants must not have had an arterial thromboembolic event, unstable angina, or myocardial infarction within 12 months prior to registration * Participants must not have active or uncontrolled infection * Participants must not have serious medical or psychiatric illness that could affect study participation in the judgement of the treating investigator * Participants must not be pregnant due to the possibility of harm to the fetus. Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen

Conditions & Interventions

Interventions:
DRUG: Capecitabine, DRUG: Temozolomide
Conditions:
Metastatic Malignant Neoplasm in the Liver, Pancreatic Neuroendocrine Tumor, Stage I Pancreatic Neuroendocrine Tumor AJCC v8, Stage II Pancreatic Neuroendocrine Tumor AJCC v8, Stage III Pancreatic Neuroendocrine Tumor AJCC v8

More Information

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Phase: PHASE2
IRB
Number:
System ID: NCT05040360
