

Testing the Addition of the Anti-Cancer Drug Tivozanib to Immunotherapy (Pembrolizumab) After Surgery to Remove All Known Sites of Kidney Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* • Histologically confirmed diagnosis of RCC with clear cell component with or without sarcomatoid features following complete resection of the primary tumor (radical or partial nephrectomy) * Note: Patients with microscopically positive soft tissue or vascular margins without gross residual disease are permitted * Intermediate-high risk RCC: * pT2 grade 4 or sarcomatoid features, N0M0 * pT3 any grade N0, M0 * High-risk RCC * pT4, any grade, N0, M0 * pT, any stage., any grade, N+, M0 * cM1 no evidence of disease (NED) RCC * Participants who have had resection of primary tumor (radical or partial nephrectomy) and resection or definitive radiation or ablation of solid, isolated, soft tissue metastases (excluding brain and bone lesions) at the time of primary tumor removal (synchronous) or ≤1 year from primary tumor removal (metachronous) * Surgery (radical or partial nephrectomy or metastasectomy or ablation) ≥ 4 weeks but ≤ 16 weeks prior to study registration with no ongoing complications from surgery * No evidence of disease at time of randomization as assessed by investigator by either CT or MRI scan of the brain and chest, abdomen and pelvis * No prior systemic treatment for RCC * Age ≥ 18 years * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (or Karnofsky ≥ 60%) * Absolute neutrophil count (ANC) ≥ 1,000/mm³ * Platelet count ≥ 100,000/mm³ * Hemoglobin ≥ 8 g/dL * Total bilirubin ≤ 3 x upper limit of normal (ULN) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) ≤ 3 x upper limit of normal (ULN) * Calculated (calc.) creatinine clearance ≥ 30 mL/min (using Cockcroft Gault equation or the estimated glomerular filtration rate from the modification of diet in renal disease trial) * Urine protein ≤ 1+ on urine analysis (UA) or urine protein creatinine ration (UPCR) < 2mg/mg * 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 is required ≤ 14 days prior to registration * HIV status: HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * Hepatitis * Hepatitis B: For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. Patients with resolved HBV infection, defined as positive hepatitis B core antibody (anti-HBc) and negative hepatitis B surface antigen (HbsAg), are eligible * Hepatitis C: Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Cardiac Disease: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class IIB or better * No history of myocarditis * No history of clinically significant pneumonitis * No uncontrolled hypertension (systolic blood pressure [BP] ≥ 150 mm Hg or diastolic BP ≥ 90 mm Hg) documented on 2 consecutive measurements taken at least 2 hours apart * No serious non-healing wound, ulcer or bone fracture within 28 days prior to registration * No serious/active infection requiring parenteral antibiotics * No moderate or severe hepatic impairment (child-Pugh B or C) * No significant bleeding disorders within 1 month prior to registration, for example: * Hematemesis, hematochezia or other gastrointestinal bleeding grade 3 or higher * Hemoptysis of pulmonary bleeding grade 3 or higher * Hematuria or other genitourinary bleeding grade 3 or higher * No history of allogeneic organ transplantation * No history of allergy of hypersensitivity to study drugs or components * No condition requiring systemic treatment with either corticosteroid (≥ 10 mg daily or prednisone equivalent) within 14 days of treatment initiation or other immunosuppressive medications within 30 days of randomization. Inhaled or topical steroids and adrenal replacement doses ≤ 10 mg daily prednisone equivalent are permitted in absence of active autoimmune disease * No active peptic ulcer disease, inflammatory bowel disease, ulcerative colitis or other gastrointestinal condition associated with increased risk of perforation; history of abdominal fistula, gastrointestinal perforation or intra-abdominal abscess within 4 weeks prior to registration * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * No patients with a history of autoimmune disease that has required systemic treatment in the past 2 years (i.e., with use of disease modifying agents, corticosteroids ≥ 10 mg/day, or immunosuppressive drugs) with the following exceptions: * Replacement therapy (e.g., thyroxine, insulin, physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed * Brief (<7 days) use of systemic corticosteroids is allowed when use is considered standard of care * Patients with vitiligo, psoriasis, type 1 diabetes mellitus, hypothyroidism, or resolved childhood asthma/atopy will not be excluded * Patients requiring intermittent use of bronchodilators, inhaled steroids, or local steroid injections will not be excluded * Patients with hypothyroidism that is stable with hormone replacement or Sjögren's syndrome will not be excluded • 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:

BIOLOGICAL: Pembrolizumab, DRUG: Tivozanib, PROCEDURE: Biospecimen Collection, PROCEDURE: MRI, PROCEDURE: Computed Tomography, PROCEDURE: Biopsy, OTHER: Questionnaire Administration

Conditions:

Clear Cell Renal Cell Carcinoma, Renal Cell Carcinoma (RCC), Stage II Renal Pelvis Cancer AJCC v8, Stage III Renal Pelvis Cancer AJCC v8

More Information

Contact(s): Aishwarya Vijendran - guprotocols@alliancenctn.org

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06661720

Thank you for choosing StudyFinder. Please visit <http://studyfinder.cctr.vcu.edu> to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.