

Focused Radiation Versus Systemic Therapy for Kidney Cancer Patients With Limited Metastasis, SOAR Study

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patient must be \geq 18 years of age * Patient must have a pathologically (histologically or cytologically) proven diagnosis of renal cell carcinoma (RCC) prior to randomization * Patient may have any RCC histology except a histology that has a sarcomatoid component * Patient must have primary site addressed by local therapy. If the primary RCC is intact, the patient must undergo local treatment to the primary before randomization * Patient must have favorable or intermediate International Metastatic RCC Database Consortium (IMDC) risk (0-2) at the time of randomization * Patient must have a total of between 2 and 5 metastatic lesions, as defined by Response Evaluation Criteria in Solid Tumors (RECIST) criteria with imaging obtained within 45 days prior to randomization * Patient must have a documentation from a radiation oncologist confirming that all sites are amenable to SABR * Patient may have received prior therapy in the adjuvant setting as long as potential trial participants have recovered from clinically significant adverse events of their most recent therapy/intervention prior to enrollment * 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 * 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 2B or better * All patients of childbearing potential must have a blood test or urine study within 14 days prior to randomization to rule out pregnancy * A patient of childbearing potential is defined as anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: * Has achieved menarche at some point * Has not undergone a hysterectomy or bilateral oophorectomy * Has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible * Patient must have a Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2 * Patients must have adequate organ and bone marrow function as per the recommended guidelines and the respective Food and Drug Administration (FDA) package insert required for the systemic therapy chosen by the treating oncologist. We recognize that patients may have varying levels of renal and liver function that will impact which systemic therapy is appropriate for the patient. We do not require all patients to have specific baseline laboratory thresholds but do ask the treating oncologist to attest that the patient has adequate organ and bone marrow function to safely receive one of the first line systemic therapies listed in the protocol as a standard of care treatment option * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of randomization are eligible for this trial. Testing for HIV is not required for entry onto the study * For patients with history of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. If no previous history, testing for HBV is not required for entry onto the study * 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. If no previous history, testing for HCV is not required for entry onto the study * In order to participate in the QOL portion of the protocol, the patient must speak one of the languages in which the NFKSI-19 and EQ-5D-5L is available * NOTE: Sites cannot translate the associated QOL forms

Exclusion Criteria:

* Patient must not have brain metastases * Patient must not have metastasis involving the following locations: ultra-central (within 2cm of carina) lung, invading gastrointestinal tract (such as esophagus, stomach, intestines, colon, rectum), skin, and scalp * Patient must not have received any prior systemic therapy (except for adjuvant setting) for metastatic RCC * Active autoimmune disease requiring ongoing therapy including systemic treatment with corticosteroids ($>$ 10 mg daily prednisone equivalents) or other immunosuppressive medications daily. Inhaled steroids and adrenal replacement steroid doses $>$ 10 mg daily prednisone equivalents are permitted in the absence of active autoimmune disease * History of severe allergic, anaphylactic or other hypersensitivity reactions to chimeric or humanized antibodies * Active tuberculosis (purified protein derivative (PPD) response without active TB is allowed) * Uncontrolled hypertension (systolic blood pressure (BP) $>$ 190mmHg or diastolic BP $>$ 110mmHg) * Major surgery within 30 days prior to randomization * Any serious (requiring hospital stay or long term rehab) non-healing wound, ulcer, or bone fracture within 30 days prior to randomization * Any arterial thrombotic (ST elevation myocardial infarction (STEMI), non-STEMI (NSTEMI), cerebrovascular accident (CVA), etc.) events within 180 days prior to randomization * Moderate or severe hepatic impairment (child-Pugh B or C) * Untreated pulmonary embolism (PE) or deep-vein thrombosis (DVT) is not allowed. Treated PE or DVT is allowed $>$ 30 days from diagnosis and when not resulting in respiratory impairment * Unstable cardiac arrhythmia within 180 days prior to randomization * History of abdominal fistula, gastrointestinal perforation, intra-abdominal abscess, bowel obstruction, or gastric outlet obstruction within 180 days prior to randomization * History of or active inflammatory bowel disease * Malabsorption syndrome within 30 days prior to randomization * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used * Patient must not expect to conceive or father children by using accepted and effective method(s) of contraception or by abstaining from sexual intercourse for the duration of their participation in the study and for 6 months after the last dose of protocol treatment

Conditions & Interventions

Interventions:

PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging, OTHER: Questionnaire Administration, PROCEDURE: Stereotactic Ablative Radiotherapy, PROCEDURE: Systemic Therapy

Conditions:

Metastatic Renal Cell Carcinoma, Stage IV Renal Cell Cancer AJCC v8

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT05863351

... questions or need assistance.