Neoadjuvant Zanzalintinib Plus Nivolumab in Patients With Locally Advanced and/or Inoperable Clear Cell Renal Cell Carcinoma With or Without Non-measurable Metastasis

NCT06794229

Status	RECRUITING
Phase	Phase 2
Sponsor	Qian Qin
Enrollment	69 participants

Plain Language Summary

This study tests a combination of zanzalintinib (a drug that cuts off tumor blood supply) and nivolumab (an immunotherapy drug) given before surgery in people with advanced or inoperable kidney cancer (clear cell renal cell carcinoma). The goal is to shrink the tumor so surgery becomes possible.

You may be eligible if...
- You are 18 or older with confirmed clear cell kidney cancer that is locally advanced or considered inoperable
- Your cancer has not spread widely to distant organs
- Your overall health is adequate (ECOG 0–1)

You may NOT be eligible if...
- You have already received treatment for this kidney cancer
- You have active autoimmune disease requiring treatment
- You have significant heart, liver, or other organ problems

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (20)

- Written informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization for release of personal health information prior to registration. NOTE: HIPAA authorization may be included in the informed consent or obtained separately.
- Age e 18 years at the time of consent.
- Eastern Cooperative Oncology Group (ECOG) Performance Status of d 1 within 30 days prior to registration.
- Histologically confirmed (i.e., tissue from primary kidney tumor of interest) diagnosis of clear cell renal cell carcinoma with or without sarcomatoid features. NOTE: biopsy should be performed at least 5 days before the first dose of study treatment and must be completely healed before dosing.
- Locally advanced (cT3/T4, N0-1) OR deemed surgically inoperable (per surgeon discretion based on factors including but not limited to surgical challenge and/or medical co-morbidities, such as renal functional reserve). Satisfying either of the criteria allows for enrollment.

... and 15 more (see full listing online)

Exclusion (48)

- Non-clear cell histology.
- Measurable metastatic disease per RECIST 1.1 criteria and other non-measurable lesions including bone metastasis, leptomeningeal disease, lymphangitic involvement of lung or skin, pathologically confirmed-malignant ascites/pleural/pericardial effusion.

• Prior systemic therapy, including zanzalintinib, nivolumab and other vascular endothelial growth factor receptor-tyrosine kinase inhibitors (VEGFR-TKIs)/immune checkpoint inhibitors(IOs), for the treatment of renal cell carcinoma.

• Prior surgery and/or radiation to the primary renal cell carcinoma tumor of interest. NOTE: prior surgery and/or radiation to other areas of the kidney (i.e., prior small kidney tumor resection or radiation) is allowed if \> 4 weeks before first dose of study treatment.

• Concomitant anticoagulation with oral anticoagulants (eg, warfarin, direct thrombin inhibitors) and platelet inhibitors (eg, clopidogrel). NOTE: For prohibited anticoagulants, subjects must have discontinued the anticoagulant within 3 days or 5 half-lives prior to first dose of study treatment, whichever is longer. Allowed anticoagulants are the following:

... and 43 more (see full listing online)

Locations (1 total)

University of Texas Southwestern Medical Center, Dallas, Texas, United States