Efficacy and Safety Comparison of Short-course Radiotherapy Followed by CapeOX Chemotherapy Plus Toripalimab With or Without Concurrent Surufatinib in Neoadjuvant Therapy for Mid-to-low Localized Rectal Cancer of High-risk Criteria

NCT07505472

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	The First Hospital of Jilin University
Enrollment	212 participants

Key Eligibility Criteria

Inclusion (2)

• \. Patients and their families are able to understand and willing to participate in this clinical study and sign the informed consent form; 2. Age: 18\~75 years old, male or female; 3. Pathologically confirmed rectal tubular adenocarcinoma; Differentiation into Grade 1-3, i.e., high, intermediate, and low-grade adenocarcinoma; pMMR/MSS phenotype; 4. Medium and low rectal cancer with the lower edge of the tumor located within 10cm from the anal verge; 5. Inclusion of treatment-naïve risk factors: cT4/cN2/mrMRF+/EMVI+ or lateral lymph node involvement.

• \. No distant metastases; 7. ECOG score 0-1; 8. Hepatitis B surface antigen (HBsAg) (-) and hepatitis B core antibody (HBcAb) (-). If HBsAg (+) or HBcAb (+), hepatitis B virus deoxyribonucleic acid (HBV-DNA) must \< 1000 copies/mL or 200 IU/mL for enrollment; 9. HCV antibody (-); 10. Negative serum or urine pregnancy test for females of childbearing age; 11. Females of childbearing potential or males with potential reproductive partners should agree to use adequate contraception (such as intrauterine devices, birth control pills, or condoms) for the duration of the study and for 120 days after the end of the study; 12. No history of pelvic radiotherapy; 13. No history of surgery or chemotherapy for rectal cancer; 14. Not accompanied by systemic infections requiring antibiotic treatment; 15. Heart, lung, liver, and kidney function can tolerate surgery;

Exclusion (1)

• \. Recurrent rectal cancer; 2. ECOG score of 2 points or above; 3. Occurrence of cardiovascular and cerebrovascular diseases within 6 months prior to the first dose: cerebrovascular accident/stroke, myocardial infarction, unstable angina, poorly controlled arrhythmias (including QTc interval e 450 ms for males and 470 ms for femalese (QTc interval is calculated by Fridericia's formula); 4. Presence of NYHA standard grade III.\~IV. cardiac insufficiency or cardiac color ultrasound examination: LVEF (left ventricular ejection fraction) \< 50%; 5. Presence of hypertension (systolic blood pressure e 140mmHg or diastolic blood pressure e90mmHg) that cannot be controlled by antihypertensive drugs; 6. Urine routine showed that urine protein was e++, and 24-hour urine protein was \> 1.0g; 7. History of immunodeficiency, including human immunodeficiency virus (HIV) infection; Other acquired, congenital immunodeficiency diseases; History of organ or bone marrow transplantation; 8. Treatment with a live vaccine within 28 days prior to the first dose, except inactivated viral vaccines for seasonal influenza; 9. Previous and current presence of known active or suspected autoimmune disease (except for patients with hypothyroidism controlled by hormone replacement therapy and type I diabetes mellitus who only require control with insulin replacement therapy); 10. Have active tuberculosis; 11. Patients with previous and current interstitial pneumonia, pneumoconiosis, radiation pneumonitis, drug-related pneumonia, severe impairment of lung function, etc., which may interfere with the detection and management of suspected drug-related pulmonary toxicity; 12. Previous treatment with other small molecule anti-angiogenic targeted drugs or antibody/drug therapy against immune checkpoints, such as PD-1 inhibitors, PD-L1, CTLA4, etc.; 13. Known history of severe allergy to PD-1 monoclonal antibody active ingredient, TKI inhibitor related components, or any investigational drug excipient; 14. Patients with organ bleeding or bleeding tendency, except for rectal primary tumor bleeding (the investigator needs to assess the bleeding risk); 15. Those who have suffered from malignant tumors in the past; 16. Received other types of anti-tumor or experimental therapy; 17. Pregnant or lactating females; 18. Patients with central nervous system diseases or abnormal mental status, which may affect the patient's participation in this study; 19. Patients with other severe, acute and chronic diseases that may increase the risk of participating in the study and study medication, and are judged by the investigator to be unsuitable for participating in the clinical study;

Locations (1 total)

the first hospital of Jilin University, Changchun, Jilin, China

https://clinicaltrials.gov/study/NCT07505472