

Optimizing Immunotherapy Combined With Neoadjuvant Chemoradiotherapy for Locally Advanced Rectal Cancer

NCT07040098

Status	RECRUITING
Phase	Phase 2
Sponsor	Cancer Institute and Hospital, Chinese Academy of Medical Sciences
Enrollment	228 participants

Key Eligibility Criteria

Inclusion (11)

- Age 18-75 years, regardless of gender;
- Pathologically confirmed rectal adenocarcinoma with immunohistochemical results indicating pMMR (proficient mismatch repair) or genetic testing confirming MSS (microsatellite stability);
- Staged as clinical stage II/III (cT3-T4N0 or cT2-4N+, no distant metastasis, per the 8th Edition AJCC Cancer Staging Manual, 2018) via MRI or endoscopic ultrasound, and meeting any one of the following:
- cT3 with tumor inferior margin d 6 cm from the anal verge;
- cT3c/d with tumor inferior margin e 6-12 cm from the anal verge; b cN2; c cT4; d MRF+ (mesorectal fascia involvement); e EMVI+ (extramural vascular invasion);
- ... and 6 more (see full listing online)

Exclusion (14)

- Prior treatment with anti-PD-1/L1 and/or anti-CTLA-4 immunotherapy or other investigational immunotherapeutic agents;
- History of severe autoimmune diseases, including active inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis), rheumatoid arthritis, scleroderma, systemic lupus erythematosus, autoimmune vasculitis (e.g., granulomatosis with polyangiitis);
- Symptomatic interstitial lung disease or active infectious/non-infectious pneumonitis;
- Risk factors for bowel perforation, such as active diverticulitis, intra-abdominal abscess, gastrointestinal (GI) obstruction, abdominal carcinomatosis, or other known predisposing conditions;
- History of other malignancies, except for cured non-melanoma skin cancer or cervical carcinoma in situ;
- ... and 9 more (see full listing online)

Locations (2 total)

Cancer Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing, China
National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital & Shenzhen Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Shenzhen, Shenzhen, China

<https://clinicaltrials.gov/study/NCT07040098>

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