Total Neoadjuvant Treatment With or Without Tislelizumab for Locally Advanced Rectal Cancer.

NCT06940388

Status	RECRUITING
Phase	Phase 2
Sponsor	brenner baruch
Enrollment	134 participants

Plain Language Summary

This trial is testing whether adding an immunotherapy drug (tislelizumab) to the standard combination treatment — chemotherapy plus radiation — before surgery improves outcomes for patients with locally advanced rectal cancer.

You may be eligible if...
- You have been diagnosed with locally advanced rectal cancer (confirmed by biopsy) that has not yet been treated
- Your tumor is within 12 cm of the anal opening
- You are aged 18 or older and are healthy enough for surgery
- You have not had any prior chemotherapy, radiation, or surgery for rectal cancer
- Your blood counts and organ function are within acceptable ranges

You may NOT be eligible if...
- You have had previous pelvic radiation for any reason
- You have active autoimmune disease
- You have received prior immunotherapy or are on immunosuppressive drugs
- You have serious heart, liver, or kidney problems

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

Key Eligibility Criteria

Inclusion (14)

- Subjects with histologically confirmed primary (non-recurrent) LARC (tumor 12 cm or less from the anal verge, as assessed by rigid proctoscopy), stage T3-4 N0 or TX N+ according to base-line pelvic MRI and PET-CT.
- Patients who are planned for TNT and are surgical candidates as determined by the treating physician.
- No prior chemotherapy, immunotherapy, radiotherapy or surgery for rectal cancer.
- No prior radiotherapy to the pelvis, for any reason.
- Able to provide the FFPE block or 10 unstained slides from the colonoscopy for confirmation of the diagnosis, CPS status and for investigational purposes.

... and 9 more (see full listing online)

Exclusion (9)

- Active or background history of an autoimmune disease except for type I diabetes mellitus, hypothyroidism requiring hormone replacement only and skin disorders (such as vitiligo, psoriasis, or alopecia) not requiring systemic treatment.
- Medical history of vasculitis.
- Prior organ transplant, including allogenic bone marrow transplantation.
- Grade \> 1 peripheral sensory neuropathy.
- Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti- CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co- stimulation or checkpoint pathways.

... and 4 more (see full listing online)

Locations (2 total)

Johannes Gutenberg-University Clinic, Mainz, Germany 1.Dept. Medicine, Prof. Peter R. Galle, Mainz, Germany
Davidoff Cancer Center, Rabin Medical Center, Beilinson Hospital, Petah Tikva, Israel