

# Personalized Long-course Radiotherapy Plus Chemotherapy With or Without Immunotherapy for LARC: PALACE Study

NCT07020247

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Status	RECRUITING
Phase	Phase 3
Sponsor	West China Hospital
Enrollment	184 participants

## Key Eligibility Criteria

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### Inclusion (14)

- Age: ≥18 years old; sex is not limited.
- Patients with stage II/III rectal cancer staged under MRI or endoscopic ultrasonography and have at least one risk factor: cT4a and invasion of intestinal lumen for more than 1/2 week (measured by MRI) cT4b(resectable) cT3c-d with EMVI+ (upper middle rectum) cN2 MRF+ (d2mm) lower rectal cancer is located on the anterior wall and tumor reaching T3 and occupying the intestinal cavity for more than 1/2 week; lower rectal cancer is mainly located on the lateral posterior wall need invading the intestinal wall (anal sphincter) ≤5mm tumor of lower rectal cancer invades the external anal sphincter or levator ani muscle (stage 4) . \[According to the 8th edition of the 2018 AJCC Cancer Staging Manual and the 2008 ESMO Lower Segment Colorectal Cancer Staging Criteria] . The preoperative T stage is referred to endoscopic ultrasonography or rectal MRI. The N stage is referred to abdominal CT. The M stage is referred to abdominal and thoracic CT. If symptoms occur, other appropriate imaging examinations are needed (cranial MRI or ECT) . Patients with contraindications to MRI can be interpreted with caution based on CT and endoluminal ultrasound staging. MDT should review the staging of all patients.
- The lower edge of lesion is less than 10cm from anal verge according to rigid sigmoidoscopy or rectal digital examination.
- No distant metastasis after a thorough examination .
- Pathological diagnosis of rectal adenocarcinoma, and Immunohistochemistry and/or genetic testing for MSS/pMMR; ... and 9 more (see full listing online)

### Exclusion (8)

- Patients who have previously received pelvic radiotherapy.
- Presence of active or progressive infection requiring systemic treatment, such as active tuberculosis, active hepatitis, etc.
- Presence of systemic diseases that are not stably controlled by the investigator, including diabetes mellitus, hypertension, liver cirrhosis, rheumatic immune diseases, and severe lung diseases.
- Have had prior or concurrent cancer distinct in primary site or histology (including synchronous colon cancer) , except for curatively treated cervical cancer in situ, Basal cell carcinoma of skin.
- Has any other disease, metabolic abnormality, physical examination abnormality, or laboratory abnormality that, in the judgment of the investigator, has reason to suspect that the patient has a disease or condition for which the study drug is inappropriate for use, or that would affect the interpretation of the study results, or place the patient in a high-risk condition. ... and 3 more (see full listing online)

## Locations (1 total)

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West China Hospital, Chengdu, Sichuan, China

<https://clinicaltrials.gov/study/NCT07020247>

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