

Reduced Length of ADT and ARTA With XRT in High-Risk Prostate Cancer (RELAX): A Randomised Trial

NCT06818682

Status	RECRUITING
Phase	Phase 2
Sponsor	Tata Memorial Centre
Enrollment	206 participants

Plain Language Summary

This randomized trial (called RELAX) is comparing two lengths of hormone therapy alongside radiation therapy for high-risk prostate cancer. It aims to find out if a shorter course of hormone treatment works just as well as the current standard.

****You may be eligible if...****

- You have biopsy-proven prostate cancer suitable for curative radiation therapy
- Your cancer is classified as high risk or very high risk (based on staging, Gleason score, or PSA level)
- You are fit enough to receive hormone therapy for up to 2 years and a newer hormonal drug for 6 months
- Your cancer has not spread to lymph nodes or distant sites (NOM0)

****You may NOT be eligible if...****

- Your cancer has a primary Gleason pattern of 5 (most aggressive grade)
- Your life expectancy is less than 2 years
- You have uncontrolled diabetes or high blood pressure that would make you ineligible for the hormonal drugs
- Your tumor extensively invades the bladder, rectum, or nearby structures

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

Key Eligibility Criteria

Inclusion (7)

- Patients with biopsy proven prostate adenocarcinoma, deemed suitable for curative- intent radiotherapy
- Clinicoradiological stage T1-T4N0M0 using PSMA-PETCT and MRI
- High risk or very high risk (as per NCCN 2023): stage T3a + OR Gleason Score 4+4 or 4+5 OR PSA 20 +
- Patient fit and able to receive ADT for 2 years
- Patient fit and able to receive ARTA for 6 months
- ... and 2 more (see full listing online)

Exclusion (9)

- Primary Gleason pattern 5 (Gleason score 5+4 or 5+5)
- Life expectancy deemed to be less than 2 years
- Uncontrolled comorbidities such as diabetes or hypertension causing ineligibility to receive ARTA
- Bulky primary disease with extensive infiltration into bladder/rectum/pelvic muscle
- Prior ADT more than 3 months before screening or prior orchiectomy
- ... and 4 more (see full listing online)

Locations (1 total)

<https://clinicaltrials.gov/study/NCT06818682>

Tata Memorial Centre, Mumbai, Maharashtra, India

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