

# Intratumoral and Systemic Hiltonol® (Poly-ICLC) in Prostate Cancer Patients on Active Surveillance

NCT06343077

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Status	RECRUITING
Phase	Phase 2
Sponsor	Ashutosh Kumar Tewari
Enrollment	114 participants

## Plain Language Summary

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This study tests a drug called Poly-ICLC (Hiltonol), an immune-stimulating agent, injected both directly into the prostate tumor and given systemically in men with low-to-intermediate risk prostate cancer who are on active surveillance (watching the cancer closely without immediately treating it).

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

- You are over 18 years old with confirmed low-grade or early intermediate-grade prostate cancer (Gleason 6 or 3+4)
- You are currently on active surveillance and have not started any hormone therapy
- Your life expectancy is at least 10 years
- You would be a candidate for surgery or radiation if your cancer progresses
- You have previously tolerated a prostate biopsy without serious complications

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

- You have high-grade prostate cancer
- You have active autoimmune disease or immune deficiency
- You are currently on immunosuppressive medications
- You have had major pelvic surgery recently
- You are unable to provide consent or comply with the study protocol

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

## Key Eligibility Criteria

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### Inclusion (35)

- Written informed consent and HIPAA authorization for release of personal health information.
  - NOTE: HIPAA authorization may be included in the informed consent or obtained separately.
  - Age  $\geq$  18 years at the time of consent.
  - ECOG Performance Status of 0-1 within 14 days prior to being registered for protocol therapy (Study Procedure Manual).
  - Histologically confirmed adenocarcinoma of the prostate (with previous diagnostic tissue available for tumor marker analysis).
- ... and 30 more (see full listing online)

### Exclusion (6)

- Received local or systemic curative therapy for prostate cancer
- Subjects with neuroendocrine tumors
- ISUP Gleason Grade Group ( $\geq$ 3), or Gleason 3+3 plus PSA  $\geq$  10 or Stage  $\geq$  T2a
- Evidence of locally advanced disease
- Subject has evidence of any other malignancy

... and 1 more (see full listing online)

<https://clinicaltrials.gov/study/NCT06343077>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

## Locations (1 total)

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Icahn School of Medicine at Mount Sinai (ISMMS), New York, New York, United States

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