Clinical Research Trial for Prostate Cancer

(Gene Vaccine Clinical Trial for Men with Newly Diagnosed Prostate Cancer Who Are Candidates for Active Surveillance)

Principal Investigator: **Mitchell H Sokoloff**
Co-Investigators: **Jennifer Yates MD and Terence R Flotte MD**

Place: **University of Massachusetts Medical Center (one of many sites) in collaboration with Advantagene Inc.**
Departments: **Urology and Gene Therapy,**

Purpose: Evaluate whether addition of a research product AdV-tk plus valacyclovir improves the clinical outcome and quality of life for patients undergoing active surveillance.

Research Product: AdV-tk and valacyclovir uses gene transfer technology to deliver a gene to a tumor to kill tumor cells

Administration:

- Randomized to test arm or control 2:1 (2/3 of patients receiving the research product)
- AdV-tk or placebo is delivered to the prostate via Transrectal ultrasound-guided injections on 2 occasions.

To be eligible, volunteers must be:

- 18 years of age and older
- Currently undergoing active surveillance and able to tolerate transrectal ultrasound guided injections and biopsies

Involvement in the study requires:

- about 8 visits over a 1year period with contact for 5 years annually to evaluate transition to radical treatment.

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www.clinicaltrials.com/