



Clinical Research Trial for Prostate Cancer

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

Principal Investigator: Mitchell H Sokoloff

Co-Investigators: Jennifer Yates MD, Terence R Flotte MD and Margaret R Humphries RN

Place: University of Massachusetts Medical Center (one of many sites) in collaboration with Advantagene Inc.

Departments: Gene Therapy and Radiation Oncology

Purpose: Evaluate whether addition of a research product ProstAtak™ to standard radiation therapy for prostate cancer improves the long-term outcome for the patients.

Research Product: ProstAtak™ 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 ProstAtak™)
- ProstAtak™ or placebo delivered to the prostate via Transrectal ultrasound-guided injections on 3 occasions.

To be eligible, volunteers must be:

- 18 years of age and older
- Planning and medically able to undergo radiation therapy and able to tolerate multiple transrectal ultrasound guided injections and biopsies

Involvement in the study requires:

- about 15 visits over a 5 year period with at least 7 of these visits to UMass Memorial Medical Center during year 1.
- annual follow up will occur after the 5 year period as in standard of care.

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www.clinicaltrials.com/