PSMA-SRT Randomized Phase 3 Trial Is Now Open at UCLA

The clinical trial will evaluate the success rate of salvage radiation therapy for recurrence of prostate cancer after prostatectomy.

September 2, 2018 By Dan Zeller

Every now and again I'm asked to share information on my blog, and this was something that is of personal interest to me given my current situation. It's from the UCLA Nuclear Medicine department and will likely be of interest to others as well.

They reference a couple of attachments in their email to me, but none were attached.

[Note: PSMA stands for prostate-specific membrane antigen, a transmembrane protein. According to the National Center for Biotechnology Information, "Studies have consistently demonstrated PSMA expression in all types of prostate tissue and increased PSMA expression in cancer tissue."]

We have the pleasure to announce the opening of a Randomized Prospective phase 3 trial of PSMA PET/CT based salvage radiation therapy (PSMA-SRT) at UCLA Nuclear Medicine (NCT03582774).

This is the first randomized prospective phase 3 trial designed to determine whether PSMA PET/CT can improve outcomes in patients with prostate cancer biochemical recurrence.

PSMA PET/CT will be free of charge for patients (100% sponsored by UCLA Nuclear Medicine).

Patients who are planned for salvage radiation therapy (SRT) for recurrence after primary prostatectomy with PSA ≥ 0.1 ng/ml are candidate.

We will randomize patients to proceed with standard SRT (control arm 1) or undergo a PSMA PET/CT scan prior SRT planning (investigational arm 2).

Patients randomized to control arm 1 will not undergo PSMA PET/CT: SRT will be performed as routinely planned per discretion of the treating radiation oncologist. Any other imaging will be allowed for SRT planning if done per routine care.

Patients assigned to arm 2 will be scheduled to undergo a PSMA PET/CT scan at UCLA Nuclear Medicine (free of charge) prior to radiation therapy planning. DICOM images and reports of PSMA

PET/CT scans will be delivered to the treating radiation oncologist.

The radiation oncologist may change the radiation plan depending on the findings of the PSMA PET/CT scan. That is, the treating radiation oncologist may use whatever dose, fractionation, and target volumes they choose, and may use concurrent ADT or not, at their discretion (please see the attached document for the radiation therapy management specifications).

The primary endpoint of the trial is the success rate of SRT measured as 5-year biochemical progression-free survival after initiation of SRT.

Patients will be followed by the UCLA Nuclear medicine research team for up to 5 years after initiation of SRT (phone/fax/secure emails with the treating radiation oncologist team and/or with the patient) every 3-6 months (routine PSA and imaging).

To enroll a patient:

- All subjects must sign the UCLA IRB approved informed consent form (ICF, attached) before enrollment and randomization.
- For UCLA patients, this will be done after a consultation with the UCLA Nuclear Medicine Team or the UCLA Radiation Oncology Team.
- For all other patients outside of UCLA, this will be done after a phone consultation with the UCLA nuclear medicine research team. Signed ICF will then be obtained by fax or email.
- The randomization number and assigned arm will be communicated by phone or email to treating physicians and patients one day after the enrollment.
- Patients randomized to control arm 1 will not need to come at UCLA and will receive SRT per routine care at the treating radiation oncologist institution.

This trial represents a good opportunity for all the patients who cannot afford the out-of-pocket costs of a research PSMA PET/CT (at UCLA: around $2,700).

Please try to spread the word as much as you can around you.

In advance I thank you very much for your collaboration.

Please don’t hesitate to contact us if you have any questions:

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Best regards

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This post originally appeared on Dan’s Journey through Prostate Cancer. It is republished with permission.

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http://beta.docker.cancerhealth.com/blog/psmasrt-randomized-phase-3-trial-now-open-ucla