Clinical trial summary (\$1802)

Comparing the Outcome of Standard Systemic Therapy Alone Versus Standard Systemic Therapy with Either Surgery or Radiation Therapy for Patients with Advanced Prostate Cancer



What is the purpose of this clinical trial?

This trial is for people who have advanced prostate cancer (cancer that's spread to other places in the body). The study asks if adding radiation therapy or prostate removal surgery to the usual treatment can help keep the cancer from getting worse.

The usual treatment for advanced prostate cancer is called standard systemic therapy (SST). SST usually includes hormone-blocking drugs. Some people also get chemotherapy drugs as part of SST.

The study will compare 2 different treatment approaches:

Usual Treatment standard systemic therapy (SST)

VS.

Study Treatment
standard systemic therapy (SST)
+
radiation therapy **or** prostate removal surgery

This trial is set up to find out:

- If adding radiation therapy or prostate removal surgery to the usual treatment can help people live longer
- If adding radiation therapy or prostate removal surgery to the usual treatment can help keep the cancer from growing or spreading
- How people's symptoms affect their quality of life



Why is this trial important?

When people with advanced prostate cancer get the usual treatment, the cancer sometimes continues to spread — and to cause pain and other problems. This trial is a chance to test whether adding radiation therapy or prostate removal surgery to the usual treatment can help prevent some of these problems.

Radiation therapy and prostate removal surgery are standard treatments for people with prostate cancer that **hasn't** spread outside the prostate. Based on past studies, researchers think these treatment options could also make a difference for people with prostate cancer that **has** spread.



Who can be in this trial?

This trial is for adults age 18 or older with prostate cancer.

This trial is for people who:

- Have advanced (metastatic) cancer
- Have been receiving hormone-blocking therapy for 28 weeks or less — or haven't received hormone-blocking therapy yet

This trial is not for people who:

- Have pure small cell carcinoma, sarcomatoid, or squamous cell carcinoma
- Already had radiation therapy or prostate removal surgery

Talk with your doctor to learn more about who can join this study.



What treatments will I get?

Step 1

Everyone in the study will receive the usual treatment. (It's okay if you already started the usual treatment before joining the trial.) This means:

- You'll get hormone-blocking drugs for 22 to 28 weeks
- You might also receive chemotherapy drugs

The usual treatment can include different combinations of drugs. You and your doctor will decide which specific drugs you'll receive.

- If your cancer **gets worse** while you're receiving the usual treatment, your part in the study will be over. Talk with your doctor about other possible treatment options.
- If your cancer **does not get worse** while you're receiving the usual treatment, you'll move on to Step 2.

If you already received hormone-blocking drugs for 22 to 28 weeks before joining this study, you'll start the study at Step 2.

Step 2

A computer will randomly assign you to one of these study groups:

Group 1: usual treatment

 You'll keep getting the treatment (SST) you received in Step 1 until the cancer gets worse or until you decide to stop because of side effects.

or

Group 2: usual treatment + radiation therapy **or** prostate removal surgery

- You'll keep getting the treatment (SST) you received in Step 1 until the cancer gets worse or until you decide to stop because of side effects.
- You'll also get radiation therapy or have surgery to remove your prostate. You and your doctor will decide which of these options you'll receive.

Your doctor will not have control over which group you're assigned to. This helps make sure the study results are fair and reliable.

Any drugs you receive during the study are approved by the FDA.



How long will I be in the trial?

If you move on to Step 2, you'll be in the study for 8 years total.

Even if you stop receiving treatment, you'll keep having visits with your study doctor so they can see how you're doing and if the cancer has gotten worse. You'll have these visits every 3 months at first, but they'll happen less often over time.



Are there costs? Will I get paid?

To learn what costs will and won't be covered, talk to your health care provider and insurance provider.

You will not be paid for joining the study.



Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at 1-800-4-CANCER
- Go to <u>www.ClinicalTrials.gov</u> and search the national clinical trial number: NCT03678025
- For a list of trial locations, visit swog.org/NCI-S1802



Key information

Protocol number: \$1802

NCT number: NCT03678025

Trial sponsor: SWOG Cancer Research Network

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Full trial title: Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary

Tumor in Metastatic Prostate Cancer

Thank you!

When you join a clinical trial, you're moving cancer medicine and patient care forward.