Clinical trial summary (S2210)

Carboplatin Chemotherapy Before Surgery For People With High-Risk Prostate Cancer and an Inherited *BRCA1* or *BRCA2* Gene Mutation

What is the purpose of this clinical trial?

This trial tests treatment for prostate cancer that is at high risk of spreading or coming back. Researchers want to find out if the chemotherapy drug carboplatin can help get rid of this type of cancer when it is given before surgery.

The trial is for people with *BRCA1* or *BRCA2* gene mutations that are inherited (passed down in a family). *BRCA* gene mutations can increase the chance of a person having high-risk prostate cancer.

This trial is set up to find out:

- If treatment with carboplatin chemotherapy before surgery can increase the chance of getting rid of high-risk prostate cancer
- If carboplatin chemotherapy helps keep levels of prostate-specific antigen (PSA) low after surgery. (Rising PSA levels can be a sign of the cancer coming back.)
- What side effects people have with carboplatin chemotherapy followed by surgery

Why is this trial important?

High-risk prostate cancer can be difficult to treat. It can grow quickly, and many patients need more treatment after surgery. Chemotherapy before surgery is proven to work well against other cancers, so doctors think the same treatment approach could benefit people with prostate cancer.

Carboplatin chemotherapy is used to treat prostate cancer that has already spread outside of the prostate. It is also approved by the Food and Drug Administration (FDA) to treat other cancers with *BRCA* gene mutations.

Who can be in this trial?

This trial is for adults, age 18 or older, with prostate cancer that has not spread to other places in the body.

This trial is for people who:

- Have high-risk prostate cancer (your doctor determines the risk level with certain tests)
- Have an inherited *BRCA1* or *BRCA2* gene mutation

This trial is not for people who:

- Have serious heart problems
- Have an active infection of hepatitis B, hepatitis C, or HIV
- Have another cancer that may make it unsafe to get treatment in this study

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

What treatments will I get?

All people who join the study will receive carboplatin chemotherapy before surgery.

You will receive 3 or 4 cycles of carboplatin. Your doctor will watch how you respond to the treatment and determine how many cycles are right for you.

After chemotherapy, you'll have surgery as usual to remove your prostate and any remaining cancer.

How long will I be in the trial?

You will be in the study for 5 years. Your study doctor will continue to follow how you are doing after surgery. You will have follow-up visits with the study team until 5 years after you started the study.

You may choose to stop treatment and leave the study at any time for any reason.

Are there costs? Will I get paid?

The study drug carboplatin is provided free to you. You will not be paid for joining the study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this 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 **www.ClinicalTrials.gov** and search using the national clinical trial number: **NCT05806515**

Key information This trial is for adults 18 years or older being

Full trial title: A Phase II Study of Neoadjuvant Carboplatin for Localized, High Risk Prostate Cancer with Germline BRCA1/2 Mutations

Protocol number: S2210

NCT number: NCT05806515

Trial sponsor: SWOG Cancer Research Network

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Thank you!

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