

# Clinical trial summary (S2312)

## Combining Cabazitaxel and Carboplatin to Treat Castrate-Resistant Prostate Cancer: Could Testing for Aggressive Variant Prostate Cancer Help Guide Treatment?



### What is the purpose of this clinical trial?

This study will test treatment for people with **castrate-resistant** prostate cancer. This form of prostate cancer does not respond to treatments that lower testosterone. It grows even when your body's testosterone is low.

**Aggressive variant prostate cancer (AVPC)** is a type of castrate-resistant cancer that grows and spreads faster due to specific features in the cancer cells.

In this study, researchers will compare the chemotherapy that is usually given for castrate-resistant prostate cancer to a new approach that adds a drug called **carboplatin** to the usual chemotherapy.

The researchers will also be testing how AVPC responds to the treatments compared to cancer that is not AVPC.

#### Usual chemotherapy

##### **cabazitaxel**

*This drug is approved by the Food and Drug Administration (FDA) to treat castrate-resistant prostate cancer*

**vs.**

#### New approach

##### **cabazitaxel + carboplatin**

*This drug combination is not approved yet by the FDA. There is evidence from previous clinical trials that it may work better than cabazitaxel to control castrate-resistant prostate cancer.*

#### **This trial is set up to find out:**

- If the combination of cabazitaxel and carboplatin works better than cabazitaxel alone to treat AVPC
- If the combination of cabazitaxel and carboplatin works better than cabazitaxel alone to treat prostate cancer that is not AVPC
- If the combination of cabazitaxel and carboplatin helps people with castrate-resistant prostate cancer live longer
- What side effects people have from treatment with cabazitaxel and carboplatin



## Why is this trial important?

This study will be larger than previous studies that tested cabazitaxel and carboplatin. Testing the drug combination with more study participants helps make sure research results are reliable. Previous studies showed that treatment with cabazitaxel and carboplatin may work better than cabazitaxel in patients with AVPC. This trial will help doctors learn if testing for AVPC could help determine which patients should receive cabazitaxel and carboplatin.



## Who can be in this trial?

This trial is for adults, age 18 and older, with castrate-resistant prostate cancer that has spread beyond the prostate.

### This trial is for people who:

- Received the drug docetaxel in previous treatment
- Have prostate cancer that has grown, spread, or shown other signs of getting worse

### This trial is not for people who:

- Received cabazitaxel or carboplatin in previous treatment
- Have signs or symptoms of disease that make it hard to do many daily activities (For example, if your symptoms often keep you in bed, the study may not be right for you.)

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



## What treatments will I get?

All study participants will have a sample of their tumor tested to find out if it is considered AVPC. Your AVPC test results will not affect the treatment you get in this study.

A computer will randomly assign you to one of 2 study groups.

### Group 1: Usual Treatment

cabazitaxel

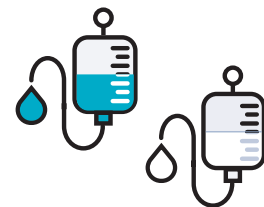


### Group 2: New Treatment Approach

cabazitaxel

+

carboplatin



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



## How long will I be in the trial?

Treatment in the study may last up to 7 months. In total, you will be in the study up to 4 years.

After treatment, your study team will continue to check how you are doing. You will have follow-up visits with the study team up to 4 years after you started the study.

You can choose to leave the study for any reason at any time.



## Are there costs? Will I get paid?

Testing for aggressive variant prostate cancer (AVPC) is provided free in this study.

Ask your health care provider and insurance provider what costs will and won't be covered in this study. 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 [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and search the national clinical trial number: **NCT06470243**
- For a list of trial locations, visit [swog.org/NCI-S2312](http://swog.org/NCI-S2312)



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

**Protocol number:** S2312

**Full trial title:** A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with Metastatic Castrate-resistant Prostate Cancer (MCRPC), Stratified by Aggressive Variant Signature

**NCT number:** NCT06470243

**Trial sponsor:** SWOG Cancer Research Network

**Publishing date:** September 3, 2024

**Thank you!**

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