Clinical trial summary (\$2409)

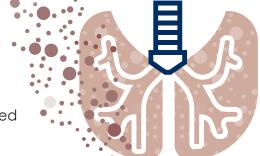
Using Biomarker Tests to Select and Test New, Personalized Treatments for Extensive Stage Small Cell Lung Cancer (PRISM Trial)



What is the purpose of this clinical trial?

This trial is testing personalized treatment options for people with extensive stage small cell lung cancer (ES-SCLC). ES-SCLC is small cell lung cancer that has spread to the other lung or other parts of the body.

There are different **subtypes** (or kinds) of ES-SCLC — and certain drugs may work better for certain subtypes. In this study, researchers will test the cancer for specific features (called **biomarkers**) to figure out which ES-SCLC subtype people have.



The goal is to match each subtype with the best **maintenance treatment**. Maintenance treatment is given after the initial (first) treatment patients get.

This trial is set up to find out:

- If testing ES-SCLC for certain biomarkers can help match people with treatments that work better for them
- If combining certain drugs with the standard treatment (durvalumab) can help keep ES-SCLC from growing or spreading
- What side effects the study treatments might cause



Why is this trial important?

The standard treatment for ES-SCLC doesn't work well for many people. But testing for biomarkers to figure out which ES-SCLC subtype people have might help doctors personalize treatments. That means this trial could lead to new and better treatment options that help more patients in the future.



Who can be in this trial?

This trial is for people who:

- Have extensive stage small cell lung cancer
- Haven't started initial treatment or have received up to 3 cycles of initial treatment
- Are age 18 or older

This trial is not for people who:

- Already finished initial treatment for extensive stage small cell lung cancer
- Have had limited stage small cell lung cancer
- Have had an organ transplant
- Are pregnant or breastfeeding



What treatments will I get?

Step 1: Initial treatment

If you haven't started initial treatment yet, you'll start getting the standard treatment as soon as possible. This includes chemotherapy drugs (cisplatin or carboplatin, plus etoposide) and an immunotherapy drug (durvalumab).

Biomarker testing

During Step 1 of the study, your care team will send a sample of your tumor to a lab for biomarker testing. If possible, they'll use a sample that was removed in a past surgery or biopsy.

The biomarker testing will show if the cancer is:



Subtype A Subtype N Subtype I



or

None of these subtypes

If the cancer is one of these subtypes, you can receive maintenance treatment in the study after you finish initial treatment. (See Step 2 on page 3.)

If the cancer is not one of these subtypes, your part in the study will be over. Your doctor will talk with you about other treatment options that may be right for you.

The testing will also show if the cancer is:

- SLFN11 positive meaning it has a protein called SLFN11
- **SLFN11 negative** meaning it doesn't have the SLFN11 protein

Knowing if the cancer is SLFN11 positive or SLFN11 negative will help your care team decide which maintenance treatment you'll get.

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Step 2: Maintenance treatment

A computer will randomly assign you to one of the study groups below. Your doctor won't have control over which group you're assigned to. This helps make sure the study results are fair and reliable.

Group 1: Usual Treatment durvalumab

Group 2: Study Treatment durvalumab

+ the drug being tested for

the cancer subtype you have



The chart below shows which drug will be given to people with each subtype — as well as when and how you'll get each drug.

Tumor subtype	Drug
Subtype PSubtype A and SLFN11 positiveSubtype N and SLFN11 positive	saruparib Saruparib is a pillYou'll take the drug once a day
Subtype A and SLFN11 negativeSubtype N and SLFN11 negative	 ceralasertib Ceralasertib is a pill You'll take the drug in cycles, and each cycle lasts 28 days You'll take the drug twice a day on the first 7 days of every cycle
• Subtype I	 You'll get monalizumab through an IV (a needle placed into a vein in your arm) You'll get the drug in cycles, and each cycle lasts 28 days You'll get the drug on Day 1 and Day 15 of each cycle



How long will I be in the trial?

You'll be in the study for up to 3 years from the time you join Step 2 (maintenance treatment). You can choose to stop treatment at any time, for any reason. Even if you stop treatment, you'll have visits with your doctor every 2 or 3 months so they can see how you're doing.



Are there costs? Will I get paid?

Biomarker testing, durvalumab, saruparib, ceralasertib, and monalizumab are provided at no cost to people in the study.

To learn more about 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 www.ClinicalTrials.gov and search the national clinical trial number: NCT06769126
- For a list of trial locations, visit swog.org/NCI-S2409



Key information

Protocol number: \$2409 NCT number: NCT06769126

Trial sponsor: SWOG Cancer Research Network

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Full trial title: PRISM: <u>Precision in SCLC</u> via a <u>M</u>ulticohort Study: Randomized Phase II Studies Evaluating Maintenance Durvalumab with or without Biomarker-Directed Therapy for Extensive Stage Small Cell Lung Cancer

(ES-SCLC)

Thank you!

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