# Clinical trial summary (\$2414)

Immunotherapy After Surgery for People with No Remaining Cancer After Standard Treatment for Early-Stage Non-Small Cell Lung Cancer



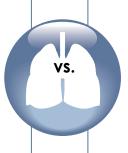
# What is the purpose of this clinical trial?

This clinical trial is for people who finished standard treatment for non-small cell lung cancer (NSCLC) before surgery and have no signs of cancer after surgery. The trial aims to learn if treatment with a drug called **durvalumab** after surgery helps keep people's cancer from coming back. Durvalumab is an **immunotherapy** drug, which means it helps your immune system fight cancer.

The study will compare 2 approaches to care after surgery:

# New Approach Treatment with durvalumab

Durvalumab is approved by the Food and Drug Administration (FDA) for treating early-stage lung cancer and lung cancer that has spread to other organs.



# Usual Approach Close monitoring

Your health care team will regularly check to see if your cancer has come back.
But you won't get any treatment to help keep it from coming back.

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

- If treatment with durvalumab after surgery helps people stay cancer-free for longer
- If treatment with durvalumab after surgery helps people live longer
- What side effects durvalumab after surgery may cause



### Why is this trial important?

Standard treatment for people with early-stage NSCLC includes chemotherapy and immunotherapy drugs — and then surgery to remove part of the lung. A doctor then carefully examines the removed piece of lung. If there are no signs of cancer, it means the treatment worked very well. But there's still a chance the cancer could come back or even spread to other parts of the body.

Doctors don't yet know whether people who have no signs of cancer after surgery will benefit from more treatment. It's possible that since the earlier treatment worked so well in these patients, further treatment is likely to help keep the cancer from coming back. But it's also possible that these patients don't need more treatment since their cancer is gone — and that further treatment would just lead to side effects and hassles.

This trial will help researchers figure out if immunotherapy after surgery does help keep the cancer from coming back — or if it isn't needed at all.





### Who can be in this trial?

This trial is for adults age 18 or older who were treated for stage 2 or 3 NSCLC.

#### This trial is for people who:

- Had FDA-approved treatment before surgery
- Have no cancer cells remaining after surgery

#### This trial is not for people who:

- Received radiation treatment after surgery
- Are still having serious side effects from treatment before surgery
- Are pregnant or breastfeeding

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



## What treatments will I get?

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

**Group 1:** study drug (durvalumab)



You'll get durvalumab once a month for up to 1 year.

Group 2: close monitoring



Your doctor will carefully monitor your health for up to 1 year.

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

Your medical care in the study will include CT scans to see if your cancer comes back. You'll get these scans more often than you would if you weren't in the study.

If the cancer comes back, taking part in this study won't stop you from getting treatment. You and your doctor can choose what care you get.



# How long will I be in the trial?

You'll be in the active part of the study for up to 1 year, and your study doctor will follow you carefully for up to 10 years total.

If you're in Group 1, you'll get durvalumab for up to 1 year. If you're in Group 2, your doctor will carefully monitor your health for up to 1 year.

No matter which group you're in, you'll have visits with your study doctor for up to 10 years, so they can see how you're doing and if your cancer comes back. At the beginning of the study, you'll have regular visits with your doctor. As time goes on, you'll visit your doctor less often.



## Are there costs? Will I get paid?

You won't need to pay for the durvalumab or the extra CT scans you'll get during 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 participating in 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: NCT06498635
- For a list of trial locations, visit swog.org/NCI-S2414



# **Key information**

Protocol number: \$2414

Full trial title: A Randomized Phase III
Trial Incorporating Pathologic Complete
Response in Participants with EarlyStage Non Small Cell Lung Cancer
to Optimize Immunotherapy in the
Adjuvant Setting (INSIGHT)

NCT number: NCT06498635

**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.