Clinical trial summary (1900K)

Targeted Treatment for Advanced Non-Small Cell Lung Cancer that has a MET Exon 14 Skipping Gene Change



What is the purpose of this clinical trial?

This study tests treatment for non-small cell lung cancer (NSCLC) that has a **MET exon 14 skipping** gene change (alteration). This abnormal change in the MET gene can cause cancer to grow and spread faster. Targeting the MET gene change is one approach doctors use to fight this rare lung cancer.

The study will test the combination of 2 drugs: **tepotinib** and **ramucirumab**. The study doctors will compare this drug combination to the usual drug treatment of tepotinib alone.

Drug	How does it work?	Is it FDA approved?
Tepotinib (TEPMETKO)	Targets abnormal MET gene changes	Yes, tepotinib is approved for people with NSCLC that has a MET exon 14 skipping gene change.
Ramucirumab (CYRAMZA)	Blocks tumors from forming new blood vessels	Yes, ramucirumab is approved for people with NSCLC.

Using tepotinib and ramucirumab together is **not** yet approved by the Food and Drug Administration (FDA). Clinical trials are now testing tepotinib combined with a second drug.

This trial is set up to find out:

- If combining tepotinib and ramucirumab can lower the chance of NSCLC growing or spreading
- If combining tepotinib and ramucirumab can lower the chance of patients developing swelling in the arms and legs as a side effect from tepotinib



Why is this trial important?

Adding ramucirumab could improve tepotinib treatment for patients. Previous research has shown that targeting the MET gene change and blocking tumor blood vessel growth can work well against NSCLC with other MET gene changes. This trial is a chance to learn if the approach also works for NSCLC with a MET exon 14 skipping gene change.

The new combination may also help reduce treatment side effects for future patients. Swelling in the arms and legs is a common side effect of tepotinib. There is evidence that using ramucirumab with tepotinib could reduce or prevent swelling.



Who can be in this trial?

This trial is for adults, age 18 or older, with non-small cell lung cancer that is stage 4 or has come back after treatment.

This trial is for people who:

- Have cancer that has a MET exon 14 skipping gene change
- Have cancer that got worse after previous treatment

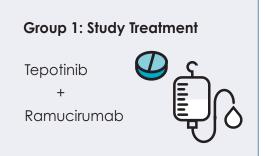
This trial is not for people who:

- Have cancer with additional gene changes that can be targeted by other drugs
- Had previous treatment using tepotinib or other drugs that target MET gene changes
- Had previous treatment using ramucirumab or similar drugs
- Have serious heart problems
- Are pregnant

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 2: Usual Treatment

Tepotinib



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?

You may be in the study for up to 3 years. You will continue getting treatment for as long as you benefit from it. You may choose to stop being in the study for any reason at any time. Your doctor may stop your treatment if side effects become too severe or your condition gets worse.

If you stop getting treatment, you will have follow-up visits with the study team until the end of 3 years.

This trial is part of a larger study called Lung-MAP. If your condition gets worse, you may have the option to join another Lung-MAP study.



Are there costs? Will I get paid?

The study drugs tepotinib and ramucirumab are provided free in this study.

Check with your health care provider and insurance provider about what costs will and won't be covered in the 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 and search the national clinical trial number: NCT06031688
- Go to <u>lung-map.org/patients</u>
- For a list of trial locations, visit swog.org/NCI-S1900K



Key information

Full trial title: A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with *MET* Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)

Protocol number: \$1900K NCT number: NCT06031688

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.