NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of capmatinib in Chinese adults with non-small cell lung cancer who have never received treatment or previously did not respond to other treatments well

Thank you!

Thank you to the participants who took part in the clinical trial for **non-small cell lung cancer (NSCLC)**. Every participant helped to learn more about the trial drug **capmatinib**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CINC280A2204

Novartis drug studied: **capmatinib,** also called **INC280**.

Sponsor: Novartis

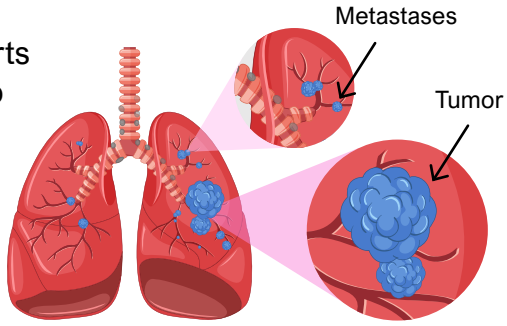
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn about the effects of **capmatinib** in Chinese adults with **non-small cell lung cancer (NSCLC)** who had never received treatment or previously did not respond to other treatments well.

NSCLC is the most common type of lung cancer. It starts when healthy lung cells become damaged and begin to grow out of control. These abnormal cells form a tumor, which can interfere with how the lungs work. Cancer is usually described in stages. In advanced NSCLC, or stages III and IV, cancer can grow and spread to other parts of the body. The growths that spread are called **metastases**. As the tumor grows, it can block airways, irritate lung tissue, and affect breathing.



NSCLC

Common symptoms of **NSCLC** are a continuous cough that worsens over time, coughing up blood or phlegm, chest pain or discomfort, shortness of breath, weight loss, weakness and loss of appetite.

One cause of **NSCLC** is changes in certain genes, called **mutations**. These mutations can affect how cells grow and divide. Some people with **NSCLC** have a mutation in a gene called **MET (Mesenchymal Epithelial Transition)**.

Normally, the MET gene helps cells grow and function properly. But when this gene is mutated, it can create abnormal MET proteins, which may lead to uncontrolled cell growth and the spread of cancer.

The trial drug, **capmatinib**, works by blocking abnormal MET proteins, which can help slow or stop the growth of cancer cells.

When this trial was planned, **capmatinib** was already approved in many countries, including the European Union and the United States, to treat advanced **NSCLC** in people with MET gene mutations. However, at the time this trial began, **capmatinib** had not yet been approved in China for treating this type of lung cancer.

Trial drug

Capmatinib also called **INC280**

Pronounced as

kap-ma-ti-nib

The trial's purpose was to answer these main questions:

- How many participants had their tumors shrink or disappear after treatment?
- What medical problems, also called adverse events, happened during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in May 2021 and ended in May 2025. Participants received treatment as long as they benefited.

At the end of this trial, the sponsor, Novartis, created a report of the trial results. This summary is based on that report.

Who was in this trial?

36 participants from **China** with **advanced NSCLC** received treatment in this trial – 18 males and 18 females. Participants' ages ranged from 53 to 82 years. Their average age was 69 years.

All participants were **Asian** by race.

Participants **could take part** in this trial if they:

- Were at least 18 years old.
- Had confirmed advanced **NSCLC** with MET mutations
- Had no previous advanced **NSCLC** treatment, or had up to 2 treatments that did not work or stopped working.

What treatments did the participants receive?

Participants received continuous treatment.

Capmatinib: **400 milligrams (mg)**, provided as tablets, taken by mouth twice a day.

The participants, researchers, and trial staff knew that all participants received **capmatinib** treatment.

What happened during this trial?

Before treatment

Up to 4 weeks

The trial staff checked to make sure the participants could be in this trial.

During treatment

For as long as participants benefited from treatment

A total of **36 participants** received treatment with **capmatinib** during this trial. They were divided into 2 groups based on their treatment history.

Group 1 15 participants	Group 2 21 participants
Included participants who had never received any treatment for **NSCLC**	Included participants who did not respond well to previous **NSCLC** treatments

Participants continued treatment as long as it provided benefit. They stopped treatment due to adverse events, their cancer got worse, or they died. They could also choose to leave the trial at any time.

After treatment

Until the trial ended

Participants were checked:

- For adverse events, for up to 1 month after the last dose.
- For their cancer status, until they could not be contacted, until they died, or until the trial ended.

Trial staff checked participants for their overall health throughout the trial.

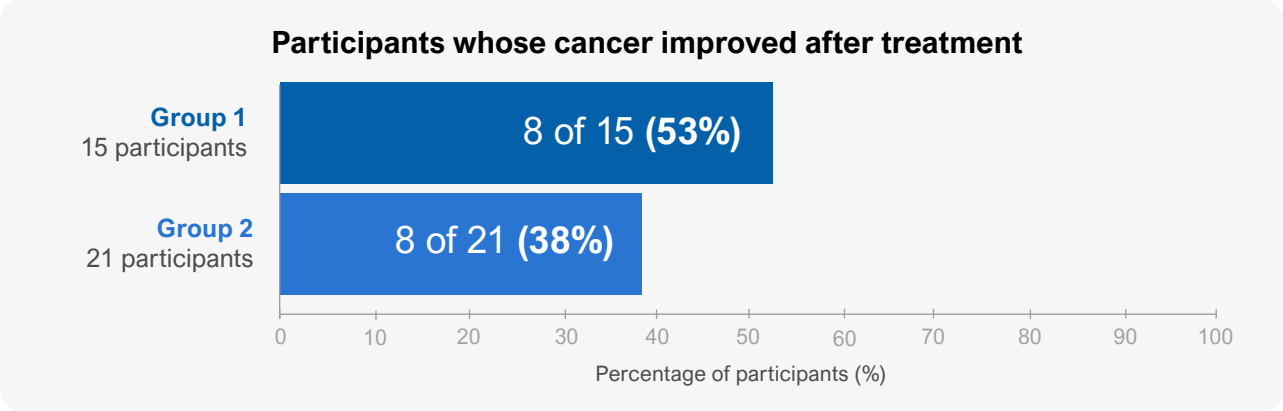
What were the main results of this trial?

How many participants had their tumors shrink or disappear after treatment?

Researchers found that **8 out of 15 participants (53%)** in **Group 1** and **8 out of 21 participants (38%)** in **Group 2** had their tumors shrink or disappear after treatment.

Trial doctors monitored how well the treatment worked by using imaging scans such as computed tomography (CT), magnetic resonance imaging (MRI), or whole-body bone scans. These scans helped track changes in participants' cancer over time.

The results below show the participants whose cancer improved after **capmatinib** treatment, based on a review by a group of independent researchers.



What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the day participants started the trial treatments until 1 month after the last dose.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

A total of **35 out of 36 participants (97%)** had adverse events, including serious and other adverse events.

- **21 participants** had serious adverse events.
- **3 participants** died due to any cause, including **NSCLC**.

The researchers concluded there were no unexpected safety concerns for **capmatinib** in this trial.

What serious adverse events did the participants have?

21 participants had serious adverse events. The table below shows the most common serious adverse events.

	Group 1 15 participants	Group 2 21 participants
Lung infection Pneumonia	3 of 15 (20%)	2 of 21 (10%)
Blockage that keeps food or liquid from passing through the intestine Intestinal obstruction	1 of 15 (7%)	1 of 21 (5%)
Lung infection due to coronavirus Coronavirus pneumonia	0 of 15 (0%)	2 of 21 (10%)

What other (not including serious) adverse events did the participants have?

The table below shows the most common other adverse events.

	Group 1 15 participants	Group 2 21 participants
Low blood calcium levels Hypocalcemia	8 of 15 (53%)	11 of 21 (52%)
Low levels of albumin, a blood protein Hypoalbuminaemia	9 of 15 (60%)	9 of 21 (43%)
Swelling of the ankles and feet Oedema peripheral	5 of 15 (33%)	10 of 21 (48%)
Low levels of red blood cells Anaemia	4 of 15 (27%)	8 of 21 (38%)
Increased liver protein Alanine aminotransferase increased	5 of 15 (33%)	6 of 21 (29%)
High levels of a waste product called creatinine in the blood Blood creatinine increased	5 of 15 (33%)	6 of 21 (29%)
Lung infection Pneumonia	2 of 15 (13%)	8 of 21 (38%)
Weight increased	4 of 15 (27%)	6 of 21 (29%)

What was learned from this trial?

Researchers learned about the effects of **capmatinib** in people with **non-small cell lung cancer (NSCLC)**.

The researchers concluded that:

- 53% of participants in Group 1 and 38% of participants in Group 2 had their tumors shrink or disappear after treatment with **capmatinib**.
- There were no unexpected safety concerns for **capmatinib** in this trial.

After the trial, in September 2025, **capmatinib** received approval for the treatment of **NSCLC** in China.

When this summary was written, **capmatinib** had been approved in China, and the sponsor had no plans for future trials of **capmatinib** in people with **NSCLC**.

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is available on the Novartis Clinical Trial Results website **www.novctrd.com**

Follow these steps to find the scientific summary:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Accept the terms **I accept** → Search for **CINC280A2204**

For more information about this trial go to this website:

clinicaltrials.gov – search using the number **NCT04677595**

Other trials of **capmatinib** may appear on the public websites above. When there, search for **capmatinib** or **INC280**.

Full clinical trial title: A phase II, multicenter, two-cohort study of oral MET inhibitor capmatinib in Chinese adult patients with EGFR wild-type (wt), ALK rearrangement negative, MET exon 14 skipping mutations, advanced non-small cell lung cancer (NSCLC) who are treatment naive or failed one or two prior lines of systemic therapy

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