NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the effects of INC280 when given before and after surgery in people with non-small cell lung cancer (NSCLC)

Thank you!

Thank you to the participants who took part in the clinical trial for **NSCLC**. Every participant helped the researchers learn more about **INC280**, also known as **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: CINC280AUS12

Drug studied: **INC280**, also known as **capmatinib**

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.

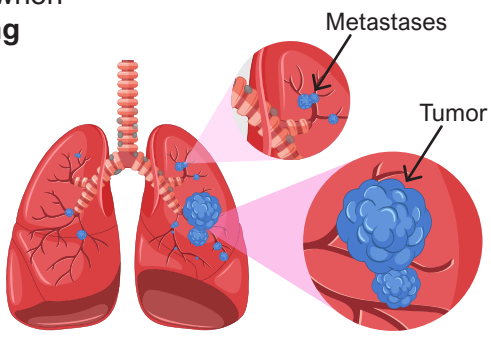
This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The main purpose of the trial was to see how well **INC280** worked when given before and after surgery in people with **non-small cell lung cancer (NSCLC)**.

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.

- In Stage I of the cancer, there is usually a small growth of cells.
- In Stage II, there are additional growths within the same organ.
- In Stage III (advanced NSCLC), the cancer can grow and spread to nearby lymph nodes, eventually reaching other parts of the body.



NSCLC

When cancer spreads beyond its original site, this is called **metastasis**. As the tumor grows, it can block airways, irritate lung tissue, and affect breathing.

Common symptoms of **NSCLC** are:

- Continuous cough that worsens
- 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.

Sometimes **NSCLC** presents at a stage that can be removed by surgery. Special cancer treatments called **neoadjuvant treatments** are given before surgery to try to shrink or stop cancer from spreading. **Adjuvant treatments** are given after surgery to try to remove the remaining cancer cells and prevent them from coming back.

The trial drug, **INC280 (capmatinib)** blocks abnormal MET proteins which can help prevent the growth of cancer cells. **INC280** is already approved in some countries to treat advanced **NSCLC** in people who have MET gene mutations.

In this trial, researchers tested if **INC280** could help shrink cancer when given as a neoadjuvant treatment before surgery and adjuvant treatment after surgery.

Drug
capmatinib

Pronounced as
kap-**ma**-ti-nib

The main questions that researchers wanted to answer in this trial were:

- How many participants had 10% or fewer cancer cells remaining in the tumor after neoadjuvant 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 August 2022 and ended in March 2024. Participants were allowed to continue with the trial treatment as long as they were benefiting from it.

The trial ended earlier than planned due to difficulties in enrolling participants. This decision was not due to any safety concerns with **INC280**.

When the trial ended, researchers created a report of the trial results. This summary is based on that report.

Who was in this trial?

4 participants from the **United States** with **NSCLC** received treatment in this trial. Participants' ages ranged from 74 to 86 years.

The number of participants by gender and race are shown below.

Gender

1 Male	3 Female

Race

3 White	1 Unknown

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

- Were at least 18 years old
- Had confirmed stage I to III **NSCLC** with either MET mutations or too many MET gene copies
- Had a tumor that could be surgically removed
- Had surgery planned within 2 weeks after the last dose of neoadjuvant treatment
- Did not receive prior treatment with MET blockers

What treatments did the participants receive?

Participants received treatment in cycles. In this trial, a cycle is a 4-week period of continuous treatment that is repeated.

INC280: 400 milligrams (mg), provided as tablets, taken by mouth twice a day.

The participants, researchers, and trial staff knew what treatment the participants were receiving. All participants took **INC280**.

What happened during this trial?

Before treatment

Up to 28 days

Trial doctors checked the participants' health to make sure they could be in this clinical trial.

During treatment

For as long as participants benefited from treatment

Neoadjuvant treatment (8 weeks before surgery)

Before their surgeries, 4 participants received 2 cycles of **INC280** treatment. Each cycle lasted 4 weeks. One participant left the trial before the surgery.

Adjuvant treatment (up to 2 years after surgery)

After surgery, participants received **INC280** as an adjuvant treatment for up to 2 years, depending on the trial doctor's decision.

However, no participants completed the full 2 years. They stopped early either by choice or due to adverse events.

Participants or their trial doctors could decide to stop the treatment at any time during the trial. They could also restart their treatment after discussing with the trial doctors.

After treatment

Up to 30 days after their last dose

Participants were checked for any medical problems for up to 30 days after their last dose of trial treatment.

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

What were the main results of this trial?

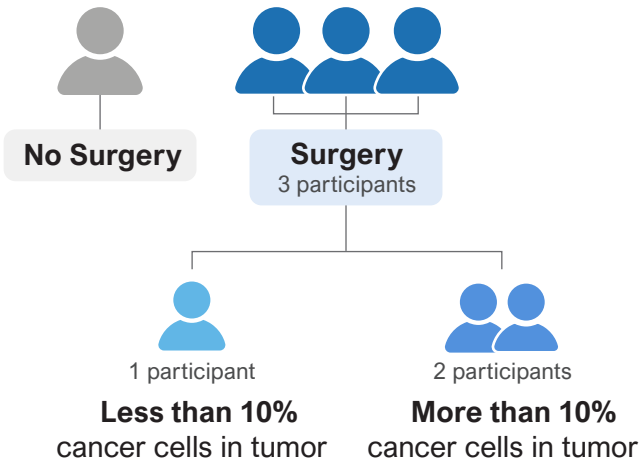
How many participants had 10% or fewer cancer cells remaining in the tumor after neoadjuvant treatment?

Researchers found that **1 out of 3 participants** had 10% or fewer cancer cells remaining in their tumors after neoadjuvant treatment.

There were not enough participants for researchers to make a meaningful conclusion about the results.

Researchers wanted to check if **INC280** neoadjuvant treatment helped shrink participants' cancer. To do this, they checked if participants had 10% or fewer cancer cells in the tumor that was removed during surgery.

The results were reported for 3 out of 4 participants. One participant left the trial before the surgery and was not included in the results.



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 track adverse events even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of treatment until 30 days 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.

All **4 participants** had adverse events.

- **3 participants** had adverse events that were considered serious.
- **2 participants** left the trial due to an adverse event.
- **1 participant** died.

How many participants had adverse events?

Adverse events are reported for participants who received at least 1 dose of **INC280**. These adverse events may or may not be caused by **INC280**.

Summary of adverse events

Participants who:	INC280 4 participants
Had at least 1 serious adverse event	3 of 4 **(75%)**
Had at least 1 other (not including serious) adverse event	4 of 4 **(100%)**
Left the trial due to an adverse event	2 of 4 **(50%)**
Died during the trial	1 of 4 **(25%)**

What serious adverse events did the participants have?

The table below shows the serious adverse events that happened during the trial. A total of 3 participants had serious adverse events, with each participant having multiple events.

Serious adverse events	INC280 4 participants
Not enough water in the body Dehydration	1 of 4 **(25%)**
Nausea	1 of 4 **(25%)**
Lack of energy or weakness Asthenia	1 of 4 **(25%)**
Fall	1 of 4 **(25%)**
Bulge or swelling in the groin area Inguinal hernia	1 of 4 **(25%)**
Bleeding in the gut Gastrointestinal hemorrhage	1 of 4 **(25%)**
Bleeding within the skull Hemorrhage intracranial	1 of 4 **(25%)**
Feeling dizziness or weakness before fainting Presyncope	1 of 4 **(25%)**
Fainting Syncope	1 of 4 **(25%)**

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

The table below shows the other (not including serious) adverse events that happened in at least 2 participants.

Other (not including serious) adverse events	INC280 4 participants
Swelling of the ankles and feet Edema peripheral	2 of 4 **(50%)**
Cough	2 of 4 **(50%)**
Diarrhea	2 of 4 **(50%)**
Dizziness	2 of 4 **(50%)**
Indigestion Dyspepsia	2 of 4 **(50%)**
Tiredness Fatigue	2 of 4 **(50%)**
Headache	2 of 4 **(50%)**
Nausea	2 of 4 **(50%)**
COVID -19	2 of 4 **(50%)**
Urinary tract infection	2 of 4 **(50%)**
Pain caused by trial procedures Procedural pain	2 of 4 **(50%)**

What was learned from this trial?

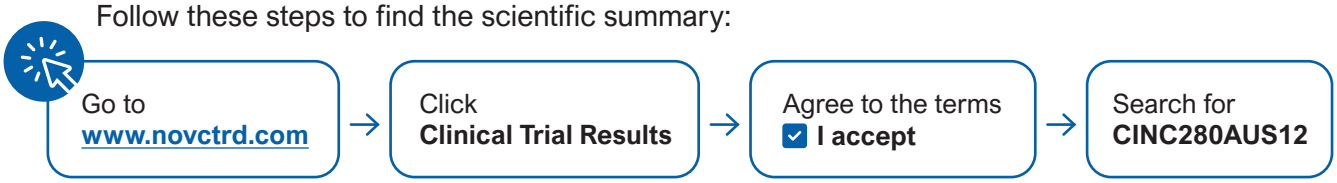
- The trial's goal was to help researchers learn more about the effects of **INC280** given before and after surgery in people with **NSCLC**.
- However, due to the low number of participants, they could not make any conclusions about its effects. They did note that there were no new safety concerns.

Currently, there are no further studies with **INC280** planned.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, www.novctrd.com.

Follow these steps to find the scientific summary:



For more information about this trial go to this website:

clinicaltrials.gov – search using the number **NCT04926831**

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

Full clinical trial title: Phase II Trial of Neoadjuvant and Adjuvant Capmatinib in Participants With Stages IB-IIIA, N2 And Selected IIIB (T3N2 Or T4N2) NSCLC With MET Exon 14 Skipping Mutation or High MET Amplification – Geometry-N

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