NOVARTIS

Clinical Trial Results Summary

A clinical trial to compare the effects of INC280 and docetaxel in previously treated 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: CINC280A2301
Drug studied: INC280, also known as capmatinib
Sponsor: Novartis

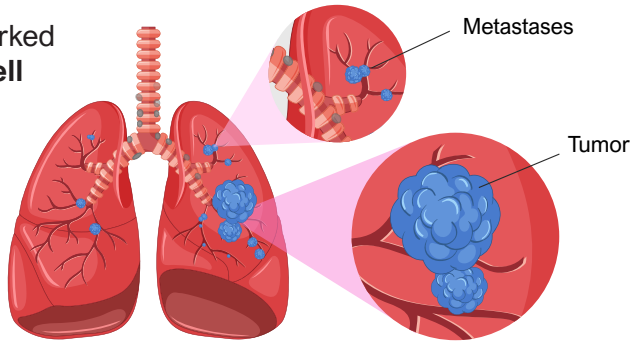
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

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 compared to **docetaxel** in people with **non-small cell lung cancer (NSCLC)**.

NSCLC is the most common type of lung cancer. It begins when the healthy cells in the lungs grow out of control. These abnormal cells grow rapidly and affect the normal functioning of the lungs. 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**.



Advanced NSCLC

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 of the causes of **NSCLC** is **gene mutations**. A mutation is a change in the gene's structure that affects its normal function. Some people with advanced NSCLC have mutations in the **Mesenchymal Epithelial Transition** or **MET** gene.

> The normal MET gene provides instructions to form MET proteins that help in normal cell growth and division. Mutations in the MET gene change the MET proteins which may cause abnormal cells to grow and spread in the body.

Currently, there are only a few drugs available for **NSCLC** with MET mutations. **Chemotherapy**, such as **docetaxel**, is one of the most common treatments for cancer. However, chemotherapy may not work against just one specific type of tumor. There are new treatments called **targeted therapies** that target specific tumor types, like **NSCLC**.

The trial drug, **INC280 (capmatinib)** is a targeted therapy that blocks abnormal MET proteins and helps the immune system destroy cancer cells. **INC280** is already approved in some countries to treat **advanced NSCLC** in people who have MET gene mutations.

Drug
capmatinib

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

In this trial, researchers wanted to see if **INC280** helped people with **NSCLC** live longer compared to **docetaxel**. **Docetaxel** is an approved chemotherapy drug for **NSCLC**.

The main questions that researchers wanted to answer were:

- How long did the participants live without their cancer getting worse or dying from any cause?
- What adverse events did participants have during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

How long was this trial?

The trial began in September 2020 and ended in November 2023. Participants were allowed to continue with the trial treatment as long as they were benefiting from it.

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

Who was in this trial?

22 participants with **NSCLC** took part in the trial, and 21 participants received treatment. One participant was assigned to the **docetaxel** group but did not receive treatment.

Participants' ages ranged from 47 to 79 years. Their average age was 67 years.

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

Gender

11 Men	11 Women

Race

17 White	3 Asian	2 Unknown

22 participants from **10 countries** took part in the trial. The map below shows the number of participants who took part in each country.

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

- Were at least 18 years old
- Had confirmed advanced stage III or IV **NSCLC**
- Had at least 1 tumor that could be measured
- Did not receive prior treatment with MET blockers

What treatments did the participants receive?

Researchers studied the following treatments, which were given in 21-day cycles:

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

Docetaxel: 75 milligrams per square meter (mg/m^2), given as a slow injection into a vein, every 3 weeks.

In this trial, a **cycle** is a 21-day treatment period, that can be repeated as needed, and during which **INC280** treatment was given daily and **docetaxel** was given on Day 1.

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

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

Up to 27 months

Participants received treatment in 21-day treatment cycles. A total of 22 participants were randomly assigned by a computer to 1 of 2 treatment groups. Of those, 21 participants received treatment.

INC280	Docetaxel
15 participants	7 participants

Participants who received docetaxel had an opportunity to receive **INC280** if their cancer worsened during the treatment period. This decision was made by an independent review committee who did not know the treatment that participants received. There were 5 participants who received **INC280** after initially receiving **docetaxel**.

After treatment

Up to 3 years

Trial staff checked the participants for:

- Any medical problems for up to 30 days after their last dose of trial treatment.
- Cancer relapse or death until the end of the trial.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

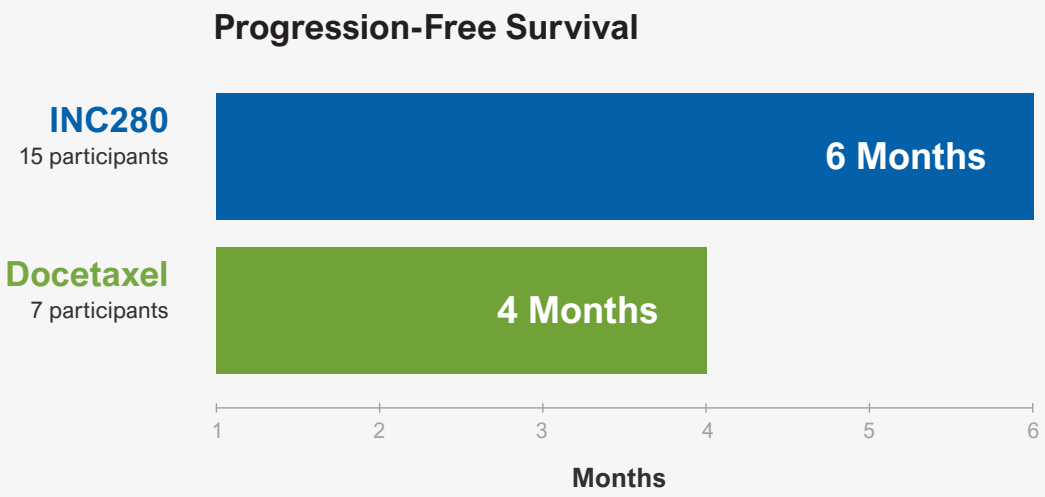
How long did the participants live without their cancer getting worse or dying from any cause?

The progression-free survival for participants who received **INC280** was 6 months. For **docetaxel**, the progression-free survival was 4 months. Researchers did not consider this difference to be meaningful.

To find out how long participants lived without their cancer worsening, researchers closely monitored the participants and checked them for **progression-free survival.**

Progression-free survival is how much time it takes from the beginning of treatment until the participants' cancer gets worse or they die.

The figure below shows the average progression-free survival for all 22 participants.



What adverse events did the participants have?

Trial doctors keep track of all **adverse events** that happen in trials, 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 up to 30 days after the last treatment.

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.

20 out of 21 participants had adverse events.

- **5 participants** had adverse events that were considered serious.
- **4 participants** left the trial due to an adverse event.
- **14 participants** died.

How many participants had adverse events?

Adverse events are reported for participants who received at least 1 dose of **INC280** or **docetaxel**. One participant was assigned to **docetaxel** group but did not receive treatment.

Summary of adverse events

Participants who:	INC280 15 participants	Docetaxel 6 participants
Had at least 1 serious adverse event	3 of 15 **(20%)**	2 of 6 **(33%)**
Had at least 1 other adverse event	14 of 15 **(93%)**	5 of 6 **(83%)**
Left the trial due to an adverse event	3 of 15 **(20%)**	1 of 6 **(17%)**
Died during the trial	9 of 15 **(60%)**	5 of 6 **(83%)**

What serious adverse events did the participants have?

The table below shows the serious adverse events that happened during the trial.

Serious adverse events	INC280 15 participants	Docetaxel 6 participants
Lung inflammation Pneumonitis	1 of 15 **(7%)**	0 of 6 **(0%)**
Extreme immune response to an infection Sepsis	1 of 15 **(7%)**	0 of 6 **(0%)**
Pain	1 of 15 **(7%)**	0 of 6 **(0%)**
Infection of the airways Respiratory tract infection	0 of 15 **(0%)**	1 of 6 **(17%)**
Chest pain	0 of 15 **(0%)**	1 of 6 **(17%)**

What other adverse events did the participants have?

The table below shows the other adverse events that happened in at least 4 participants in either group.

Other adverse events	INC280 15 participants	Docetaxel 6 participants
Swelling of the ankles and feet Oedema peripheral	10 of 15 **(67%)**	0 of 6 **(0%)**
Vomiting	6 of 15 **(40%)**	0 of 6 **(0%)**
Nausea	5 of 15 **(33%)**	1 of 6 **(17%)**
Cough	5 of 15 **(33%)**	1 of 6 **(17%)**
Weakness Asthenia	4 of 15 **(27%)**	2 of 6 **(33%)**
Hair loss Alopecia	1 of 15 **(7%)**	4 of 6 **(67%)**
Constipation	4 of 15 **(27%)**	1 of 6 **(17%)**
Decreased appetite	4 of 15 **(27%)**	1 of 6 **(17%)**
High levels of a waste product called creatinine in the blood Blood creatinine increased	4 of 15 **(27%)**	0 of 6 **(0%)**

What was learned from this trial?

This trial helped researchers learn about the effects of **INC280** as compared to **docetaxel** in people with **NSCLC**.

The researchers concluded that:

- The difference in the progression-free survival between the **INC280** and **docetaxel** groups was not considered meaningful.
- There were no new, unexpected safety concerns with **INC280**.

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:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Agree to the terms ☑ **I agree** → Search for **CINC280A2301**

For more information about this trial go to any of the following websites:

- clinicaltrials.gov – search using the number **NCT04427072**
- clinicaltrialsregister.eu/ctr-search/search – search using the number **2020-001578-31**

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

Full clinical trial title: A Phase III, Randomized, Controlled, Open-Label, Multicenter, Global Study Of Capmatinib Versus Soc Docetaxel Chemotherapy In Previously Treated Patients With EGFR Wt, ALK Negative, Locally Advanced Or Metastatic (Stage IIIB/IIIC Or IV) NSCLC Harboring MET Exon 14 Skipping Mutation (MetΔex14)

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