# Summary of Clinical Trial Results

## A study to find out if taking different forms of a medicine (GDC-9545) results in the same amount of medicine in your body – and the effect of food on the medicine

See the end of the summary for the full title of the study.

## About this summary

This is a summary of the results of a clinical trial (called a "study" in this document).

This summary is written for:

- Members of the public.
- People who took part in the study – the **participants**.

This summary is based on information known at the time of writing.

The study started in February 2020 and finished in April 2020. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- **This means that you should not make decisions based on this one summary.**
- **Always speak to your doctor before making any decisions about your treatment.**

### Contents of the summary



### Thank you to the people who took part in this study

The people who took part have helped researchers answer important questions about the study medicine that was prepared in two different forms.

## Key information about this study

- This study was done to find out if taking different forms of the same medicine resulted in getting the same amount of medicine in the body.
- People who participated in this study were given a medicine, called, "GDC-9545", in tablet and capsule forms.
- The effect of taking the medicine with and without food was also studied.
- This study included 18 people in one country.
- The main finding was that taking GDC-9545 in different forms (tablet and capsule) resulted in similar amounts of medicine in the body.
- Less medicine was absorbed when taken with food. Absorption was also slower when taken with food.
- There were no serious side effects caused by the medicine in this study.

## 1. General information about this study

### Why was this study done?

Breast cancer is the most common type of cancer in women. In many patients, the cancer produces a protein called "**estrogen receptor**", or "**ER**" for short.

- If the ER protein is present on cancer cells, the disease is known as "ER+ breast cancer".
- A protein in the body called "**estrogen**", which is a type of hormone, can bind to the ER protein.
- When estrogen is bound to ER, the cancer cells are able to grow and spread.

Treatments for ER+ breast cancers include medicines that interfere with the formation of estrogen or its activity.

However, many patients have their cancers come back after treatment – the cancer "**relapses**". In some patients, the cancer stops responding to treatment – the cancer becomes "**resistant**".

GDC-9545 is a new type of medicine that may be useful for treating ER+ breast cancer.

This study was done to find out if healthy people ended up with the same amount of medicine in their body whether they took GDC-9545 in tablet form or capsule form.

## What was the medicine being studied?

The study medicine was called, "**GDC-9545**".

- GDC-9545 is a study medicine taken by mouth.
- GDC-9545 binds to the ER protein in cancer cells. This reduces the ability of estrogen to bind to the ER protein. GDC-9545 also breaks down the ER protein.
- GDC-9545 is a type of study medicine known as a "hormone" or "endocrine therapy".
- GDC-9545 may be useful for patients with ER+ breast cancer.

## What did researchers want to find out?

Researchers did this study to compare two forms of GDC-9545.

**The main question that researchers wanted to answer was:**

1. Did different forms of GDC-9545 (tablets and capsules) deliver the same amount of medicine in people?

**Other questions that researchers wanted to answer included:**

2. What was the effect of taking GDC-9545 with and without food?

## What kind of study was this?

There are several terms to describe this study:

**Phase 1 study**
This was one of the early studies for this study medicine.

**Randomized study**
People were randomly assigned to different groups. Being randomized means it was decided by chance which group you joined.

**Open label study**
This study was open label, which means that after you were randomly placed in a group, you and the researchers knew which form of the medicine you were getting.

**Crossover study**
There were 3 different treatments being tested in this study. When participants completed one treatment, they "crossed over" to another treatment.

## When and where did the study take place?

The study started in February 2020 and finished in April 2020. This summary was written after the study had ended.

The study took place at one study center in the United States.

## 2. Who took part in this study?

There were 18 women, between the ages of 39 and 63, who took part in this study.

**People could take part in the study if:**

- They were between 18 and 65 years old.
- They were women who were unable to get pregnant due to age or surgical procedure.
- They had a normal weight or were overweight, but not obese.
- They were in good health and blood test results were normal.
- Apart from blood samples analyzed for the study, they also agreed to have blood samples stored for long periods (archived) for research use later.

**People could not take part in the study if:**

- They had a history of medical illness, mental illness, or food or medicine allergies.
- They had stomach or intestine surgery that could interfere with the absorption of the study medicine.
- They had a history of drug or alcohol addiction within the last year.
- They used tobacco or nicotine within the last 6 months.
- They had used certain medicines during certain periods before the study.
- They had recently donated blood or plasma.

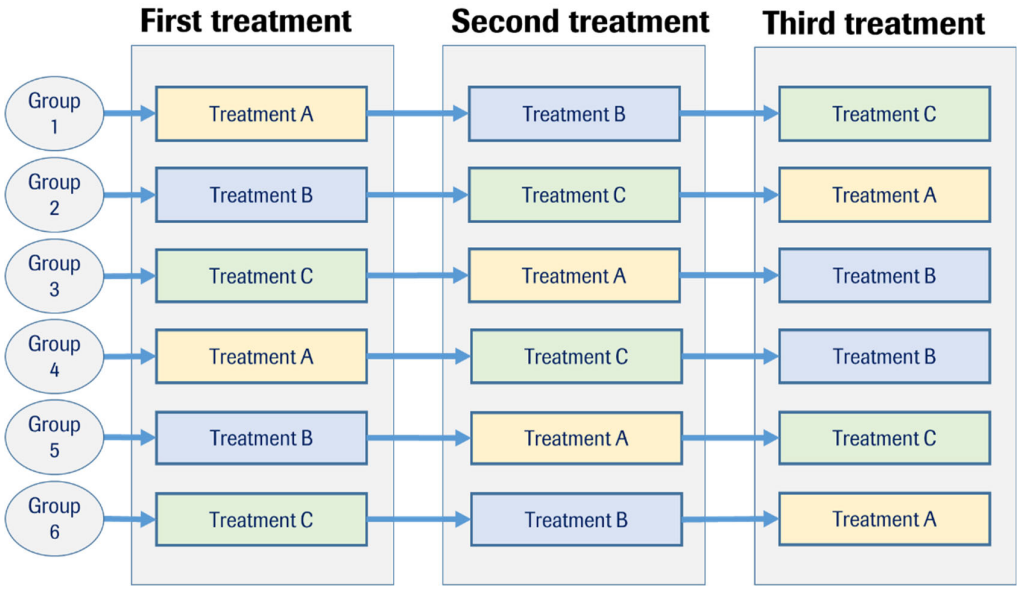
## 3. What happened during the study?

During the study, the study participants joined one of 6 groups. There were 3 women in each group. It was decided by chance (randomly) which group each participant joined.

Each person got **3 treatments** of one dose of GDC-9545 30 mg. The treatments were:

| Treatment A | Treatment B | Treatment C |
|---|---|---|
| • Tablets (3 x 10 mg)<br>• Taken after 8 h fast | • Capsule 30 mg<br>• Taken after 8 h fast | • Capsule 30 mg<br>• Taken with food |

The order in which the 3 treatments were given to the 6 groups were:




**Taking the medicine without food:**

For Treatments A and B, participants took their tablets by mouth with water after an overnight fast of about 8 hours (no food for 8 hours before taking the medicine).

They were not allowed to eat any food for 4 hours after taking the medicine.

Participants could drink water at all times except for 1 hour before and 2 hours after taking the medicine.

**Taking the medicine with food:**

For Treatment C, participants took their tablets by mouth with water within 30 minutes of eating a high-fat breakfast.

They were not allowed to eat any food for 4 hours after taking the medicine.

Participants could drink water at all times except for 1 hour before and 2 hours after taking the medicine.

**What happened during each treatment**

- One day before getting their treatment (Day -1), participants checked in at the clinic.
- Participants got their treatment on Day 1 and returned home on Day 8.
- While staying at the clinic (Day -1 to Day 8), blood samples were collected at various times. Participants were observed for any side effects from the medicine.
- Participants returned to the clinic for the next treatment after at least 10 days had passed since the prior treatment. They received a total of 3 treatments.
- Participants returned to the clinic for a last visit around 12 to 14 days after the last treatment.

## 4. What were the results of the study?

### **Question 1:** Did different forms of GDC-9545 (tablets and capsules) deliver the same amount of medicine in people?

Researchers looked at blood samples collected from when participants got Treatment A (tablets) and compared that to when they got Treatment B (capsule).

They found that the **tablet form** and **capsule form** of the study medicine **delivered the same amount** of medicine in the body when taken without food.

In addition, the speed (rate) at which the medicine was absorbed into the body was the same for both treatments.

### **Question 2:** What was the effect of taking GDC-9545 with and without food?

Researchers looked at blood samples collected from when people got Treatment B (capsules with food) and compared that to when they got Treatment C (capsules without food).

There was **more medicine absorbed** into the body with it was **taken without food**.

In addition, the medicine was **absorbed at a faster speed (rate)** when it was **taken without food**.

## 5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happened during the study.

- They are described in this summary because the study doctor believes the side effects were related to the treatments in the study.
- Not all of the people in this study had all of the side effects.
- Side effects may be mild to very serious and can be different from person to person.
- It is important to be aware that the side effects reported here are from this single study. Therefore, the side effects shown here may be different from those seen in other studies, or those that appear on the medicine leaflet.
- Serious and common side effects are listed in the following sections.

### Serious side effects

A side effect is considered "serious" if it is life threatening, needs hospital care, or causes lasting problems.

There were **no serious side effects** reported in this study.

There were no deaths reported in this study.

### Most common side effects

Five participants (28%) had a side effect that was not serious, but **was thought to be caused by the study medicine**. These included:

- Abnormal blood test results (increased creatinine phosphokinase) reported by 2 people.
- Difficult bowel movements (constipation) reported by one person.
- Reddening of the skin (flushing) reported by one person.
- Headache reported by one person.

No one in this study stopped the treatments because of side effects.

### Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see section 8.

## 6. How has this study helped research?

The information presented here is from a single study of 18 healthy people. These results helped researchers learn more about the two forms of the study medicine – GDC-9545 in tablet form and in capsule form.

- Researchers found out that both forms of GDC-9545 deliver the same amount of medicine in the body when taken without food.
- They also learned that taking GDC-9545 with food reduces the amount of medicine that gets absorbed into the body. The speed of absorption was lower when the medicine was taken with food.

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## 7. Are there plans for other studies?

Studies with GDC-9545 are still happening, and further studies are planned.

## 8. Where can I find more information?

You can find more information about this study on the websites listed below:

- https://clinicaltrials.gov/ct2/show/results/NCT04274075
- https://forpatients.roche.com/en/trials/healthy-volunteers/evaluation-of-the-relative-bioavailability-and-food-eff-96225.html

### Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/About.html
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

## Who organized and paid for this study?

This study was organized and paid for by Genentech, Inc., South San Francisco, CA, USA. Genentech is part of F. Hoffmann-La Roche Ltd., with headquarters in Basel, Switzerland.

## Full title of the study and other identifying information

The full title of this study is:

> A phase 1, open-label, single-dose, randomized, three-period crossover study to evaluate the relative bioavailability and food effect of GDC-9545 in healthy female subjects of non-childbearing potential.

- The protocol number for this study is **GP42006**.
- The ClinicalTrials.gov identifier for this study is **NCT04274075**.