Clinical Trial Results – Layperson Summary

A study to find out if people get the same amount of medicine when they take the two different forms

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; we will refer to the clinical trial as a "study" in this document.

This summary is written for:

- members of the public
- people who took part in the study

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

The study started in December, 2018, and finished in February, 2019. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. Many people volunteer in several studies to help us 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 to answer important questions about the study medicine.

Key information about this study

- This study was done to find out if taking two different forms of the same medicine resulted in getting the same amount of medicine in the body.
- In this study, people took the study medicine as Form A and Form C – it was decided by chance which order each person took the two forms in.
- This study included 28 people at one study center USA.
- The main finding was that Form A and Form C were the same – people who took them had the same amounts of medicine in their blood.
- People who took Form A or Form C did not have any side effects that were related to the medicine.
- There were no serious side effects either.
- At the time of writing this summary, the study had ended.

1. General information about this study

Why was this study done?

Kinases are specialized proteins that carry out certain kinds of chemical reactions inside the cell as well as on the surface of cells. Researchers have created a medicine that stops kinases in cancer cells from working. This medicine was made one way and called “Form A”. Now, researchers have come up with another way to make the same medicine. The medicine made the second way is called “Form C”.

In this study researchers wanted to find out if people get the same amount of medicine when they take Form A and Form C.

What were the study medicines?

Entrectinib is the name of a medicine in this study.

- This medicine is also known as RO7102122 and RXDX-101.
- Entrectinib is a medicine for treating different kinds of cancer.
- The medicine made one way was called “**entrectinib Form A**”.
- The medicine made a second way was called “**entrectinib Form C**”.

What did researchers want to find out?

- Researchers did this study to compare entrectinib Form A with entrectinib Form C
- They wanted to know if there were any differences in the amount of medicine that got into the body when people took the two different forms.
- They also wanted to find out how many people had side effects when taking each form of the medicine during this study.

The main question that researchers wanted to answer was:

1. Is the amount of medicine that gets into the body from entrectinib Form A the same as the amount of medicine that gets into the body from entrectinib Form C?

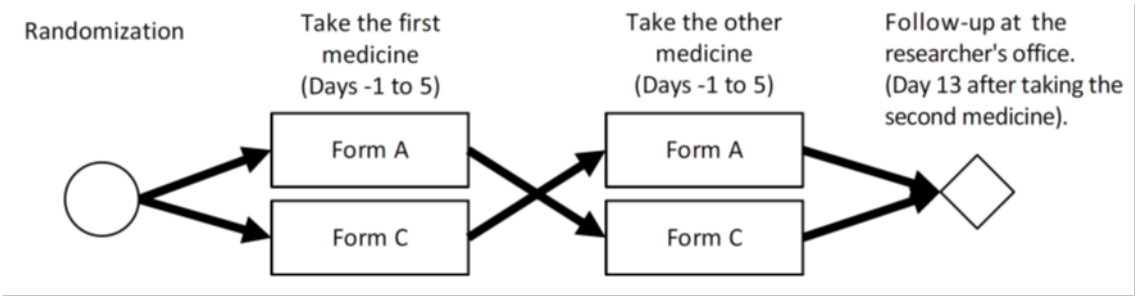
Other questions that researchers wanted to answer included:

2. Were there side effects from taking Form A and Form C?

What kind of study was this?

There are several ways to describe different parts of the study design.

- **Randomized study**
  People were randomly assigned to a group that got Form A of the medicine first and then Form C, or they were randomly assigned to a group that got Form C of the medicine first and then Form A.
  Being randomized means it was decided by chance which group you got.
- **Open-label study**
  This study was open label which means that after you were randomly placed in a group, you knew what form of the medicine you were getting.
- **Two-treatment study**
  After you took one form of the medicine that you were assigned, you then got to take the other form on a later day. By the time the study was completed, everyone got to take both forms of the medicine.
- **Two-period study**
  After taking the first form of the medicine that you were assigned to, you had to wait a few days before you could take the other form. This means the two forms of the medicine were taken a few days apart.
- **Two-way crossover study**
  People who were assigned to take "Form A" took the medicine. Then, a few days later, they "crossed over" and became the group that was given "Form C" of the medicine. The same happened in reverse to people in the other group.



When and where did the study take place?

The study started in December, 2018, and finished in February, 2019.

- This summary was written after the study had ended.
- The study took place at one study center in the United States of America.

2. Who took part in this study?

In this study, 28 healthy people who were over 18 years of age took part. Their ages were between 21 years to 57 years. There were 17 men and 11 women in this study.

Researchers did medical tests and talked to people interested in this study to make sure that they could take part in this study.

Requirements for participating in this study:

- Be 18 to 60 years old and have a healthy weight.
- Be generally healthy and blood test results must be normal.
- Men and women who could have children had to agree to use birth control while on this study.

What disqualified you from the study

- People could not take part in this study if they had certain medical conditions.
- Women who were breastfeeding their babies could not be on the study.
- Those who were sick within 4 weeks before the study, or if they had recently participated in another study could not be on this study.
- People who had recently used certain other medicines could not be on this study.

3. What happened during the study?

During the study, people took two different forms of the same medicine.

Conditions for taking the medicine:

- No food was allowed for 8 hours before taking the medicine and for 4 hours after taking the medicine. So, the medicine was taken on an empty stomach in the morning.
- People were asked to limit drinking water from 1 hour before taking the medicine to 1 hour after taking the medicine.

First study treatment:

- Everyone got **a single 200 mg dose of entrectinib** – the study medicine.
- Half of the people got **Form A of** the medicine.
- The other half got **Form C of** the medicine.
- People in both groups stayed at the study center for 5 days after taking the medicine.

Fifteen days after taking the first 200 mg dose of entrectinib in either Form A or Form C, everyone was asked to come back to the study center to take the medicine in the other form.

Second study treatment:

- Everyone got **a single 200 mg dose of entrectinib** – the study medicine.
- Those who had taken Form A of the medicine first – they now took Form C.
- Those who had taken Form C before – now they could take Form A.
- Once again, everyone stayed at the study center for 5 days after taking the medicine.

What happened during the study:

- Each time after taking the medicine researchers did tests to measure the amount of the medicine in the body, and did tests and made observations to look at any side effects of taking the medicine.
- The study ended 13 days after taking the second medicine.

4. What were the results of the study?

Question 1: Is the amount of medicine that gets into the body from entrectinib Form A the same as the amount of medicine that gets into the body from entrectinib Form C?

It did not matter whether people took Form A or Form C of the study medicine - the amount of entrectinib that got into the blood was the same.

Question 2: What were the side effects and any other effects of Form A and Form C of the study medicine?

The study medicine was safe when given to people either in Form A or Form C. There were no side effects that were thought to be caused by the study medicine.

5. What were the side effects?

Side effects (also known as “adverse reactions”) are unwanted effects or medical problems (such as a headache) that happen during the study.

- Not every patient in a study has all of the side effects seen in the study.
- Common side effects and serious side effects are listed in the following sections.

Most common side effects

While medical problems were reported by people after they took the study medicine, none of these were believed to be side effects caused by the study medicine. .

Medical problems in this study were:

- Two people had insect bites.
- One person had a cough.
- One person had a stuffy nose.

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.

6. How has this study helped research?

The results presented here are from a single study of 28 healthy people who took the study medicine – entrectinib - in Form A and in Form C. These results helped researchers learn that both forms deliver the same amount of medicine in the body.

There were no side effects or serious side effects that were thought to be related to the study medicine in this study.

No single study can tell us everything about the risks and benefits of a medicine. 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.

7. Are there plans for other studies?

Other studies can be found by doing a search for the term, “entrectinib” at the following website: https://forpatients.roche.com/

At the time of writing this summary, some studies with entrectinib were complete, while others were in progress.

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/NCT03796013
- https://forpatients.roche.com/en/trials/healthy-volunteers/a-study-to-investigate-the-bioequivalence-of-two-differ-55333.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 us” form. https://forpatients.roche.com/en/trials/healthy-volunteers/a-study-to-investigate-the-bioequivalence-of-two-differ-55333.html
- Or 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 center.

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 randomized, open-label, two-treatment, two-period, two-way crossover study to investigate the bioequivalence of entrectinib polymorph forms A and C under fasted conditions in healthy subjects”.

- The protocol number for this study is: **GP41049.**
- The ClinicalTrials.gov identifier for this study is: **NCT03796013.**