

Clinical Results Summary

A clinical study to learn how the body absorbs, breaks down, and removes quizartinib in healthy male participants

Protocol number: AC220-006

Thank You!



Daiichi Sankyo, Inc., the sponsor of this study, would like to thank the participants who took part in this study for quizartinib, also known as AC220. Each participant helped to advance medical research for people affected with acute myeloid leukemia. Their contribution to medicine and healthcare is greatly appreciated.

Important note: This summary only shows the results of a single study. Other studies may have different findings. Researchers and health authorities look at the results of many studies to understand which treatments work and how they work. It takes a lot of people in many studies around the world to advance medical science and healthcare.

Do not use the results of this study to make health decisions. Please talk to a doctor before changing any treatment you are taking or if you have any questions about these study results.

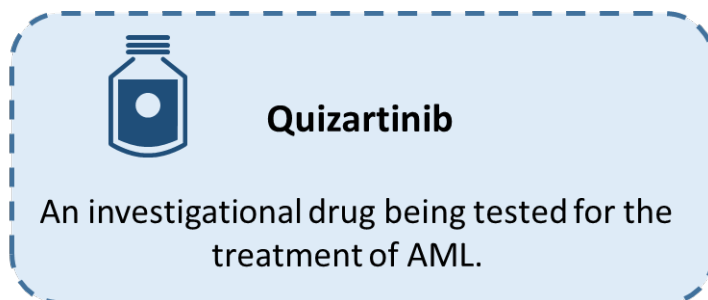
What was the main purpose of this study?

Quizartinib, also known as AC220, is an investigational drug that is being tested to treat people with a type of blood cancer called acute myeloid leukemia, or AML.

In this study, researchers wanted to find out how the body of a healthy person absorbs, breaks down, and removes quizartinib. This can guide them to what may happen in patients with AML. Healthy person means people without any health problems.

Treatment given in this study

The treatment given in this study was:



The total amount of quizartinib given during this study consisted of quizartinib and a very small amount of quizartinib with a radioactive tag. This tag helped researchers to monitor and track quizartinib and its breakdown products in the body.

Main purposes of this study

The main questions the researchers wanted to answer in this study were:

What are the plasma* levels of quizartinib and its active breakdown product AC886** in healthy participants?

How is quizartinib removed from the body when given to healthy participants?

**Plasma is the fluid part of the blood. It contains different components of the blood that are necessary for life and health such as hormones, proteins, etc.*

***The body breaks down quizartinib into another product called AC886. AC886 has similar effects in the body to quizartinib.*

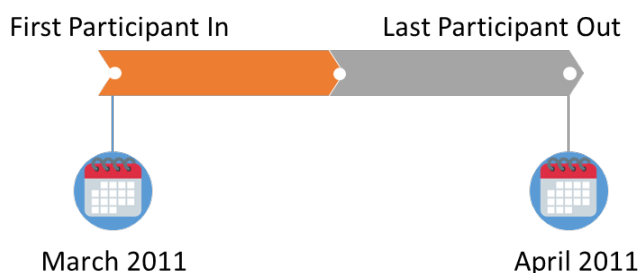
Other purpose of this study

Researchers also wanted to answer the following question:

- What side effects could the healthy participants develop during this study?

There were some additional questions that researchers wanted to answer but these are not discussed in this summary.

How long was this study?



An individual participant could have been in this study for up to 1 month.


The first participant enrolled in this study in March 2011 and the last participant completed the study in April 2011. The study was completed as planned and a study report was created. This summary is based on that report.

Who was in this study?

This study included participants from the United States.

Participants could take part in this study if they:

- were healthy and between 18 to 45 years of age, and
- had normal organ and body functions



In this study

6 men took part

They had an average age of **29 years**

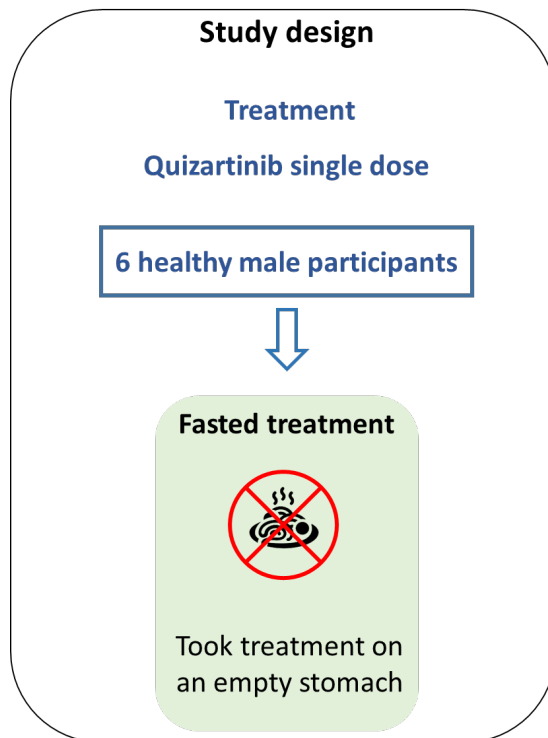
What happened during this study?

This was a Phase 1 study. Phase 1 studies are done to find out how a new study treatment works in a small number of participants. This helps researchers understand what happens to the study treatment in the body, and if there are any side effects.

This study was “open label”. This means that both the researchers and the participants knew what treatment was given.

Participants were screened to find out if they could take part in the study. On the day before dosing, participants were admitted to the study site for a 10 to 14-day in-house stay. All participants received a single oral dose of the study treatment in liquid form on an empty stomach. The dose consisted of 60 milligrams (mg) of a mix of quizartinib and a very small amount of quizartinib with a radioactive tag.

Researchers took blood, urine, and stool samples from participants at defined time points to find out the levels of quizartinib and AC886. Researchers monitored the participants' health throughout the study. The participants were discharged from the study site on Day 15 at the latest.



What were the key results of this study?

Key results from this study are shown for the total group of participants as average results. This summary does not show the results from each individual participant. An individual participant's results could be different from the total group of participants.

What were the plasma levels of quizartinib and its active breakdown product AC886 in healthy participants?

To answer this question, researchers took blood samples from participants at defined time points. However, these blood samples were not processed correctly. Therefore, the measurement of the plasma levels of quizartinib and its active breakdown product AC886 were not precise.

How was quizartinib removed from the body when given to healthy participants?

The researchers also wanted to find out how quizartinib was removed from the body when given to healthy participants. They found that the main route through which quizartinib was removed from the body was in the feces. 76% of quizartinib was removed through the feces while less than 2% was removed through the urine.

What were the other results of this study?

What side effects did the participants develop during this study?

Side effects are medical problems that happened during the study, which the study doctor (investigator) thought could be related to the treatments in the study. This section provides a summary of side effects related to the study treatment.

Side effects are considered serious if they cause death, are life-threatening, cause disability, cause lasting problems, cause birth defects, or require hospitalization. Some participants stop study treatment because of side effects.

Side effects other than those related to quizartinib are not reported here.

How many participants had serious side effects?

No participant had a serious side effect or died due to a side effect during this study.

How many participants had side effects?

Only 1 participant had a side effect of diarrhea during the study.

How many participants had to stop treatment because of side effects?

None of the participants in the study stopped treatment due to side effects.

How was this study useful for patients and researchers?

This study was designed to help the researchers learn about the plasma levels of quizartinib and its breakdown product AC886 in healthy participants. The study also helped researcher to understand how quizartinib was removed from the body of healthy participants. It was not possible to determine the plasma levels of quizartinib and AC886 because of an issue with the blood sample processing during the study. However, researchers did find out that the major route by which quizartinib was removed from the body was through the feces.

Findings from this study may be used in other studies with quizartinib. Other studies for quizartinib are ongoing.

Please remember, this summary only shows the results of a single study. Other studies may have different findings. Please talk to a doctor before changing any treatment you are taking or if you have any questions about these study results.

Full study title: A Phase 1 Study of the Absorption, Metabolism, and Elimination of AC220 in Healthy Normal Male Volunteers

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