Daiichi-Sankyo

Clinical Results Summary

A clinical study to find out how much quizartinib reaches the bloodstream when given to healthy male participants by mouth compared to administration into the vein

Protocol number: AC220-A-U107

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 and knowledge for people affected with a type of blood cancer called acute myeloid leukemia. Their contribution to medicine and healthcare is greatly

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.

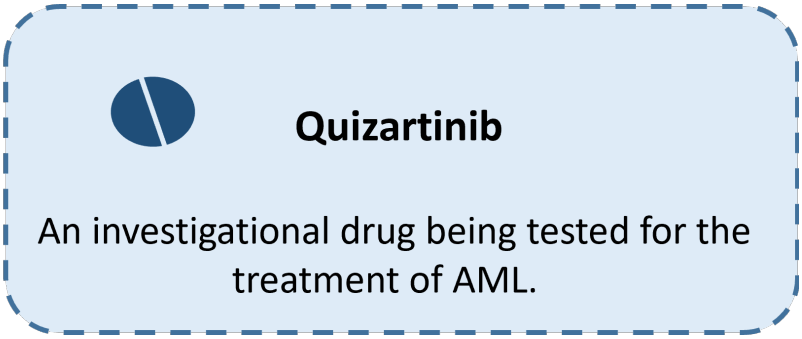
What was the main purpose of this study?

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 or people with other types of blood cancer.

In this study, researchers wanted to find out how much quizartinib reaches the bloodstream when given by mouth to healthy male participants. This means people without any health problems.

Treatment given in this study

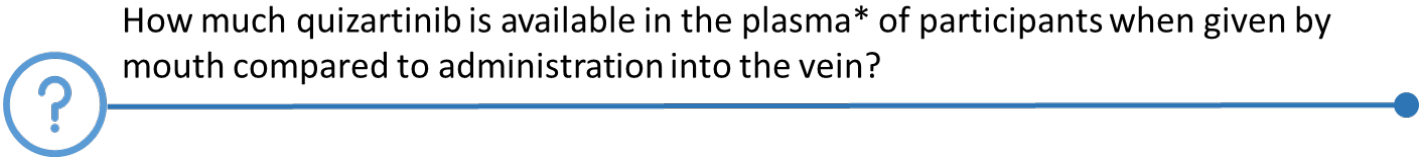
The treatment given in this study was:



Quizartinib was given by mouth as tablets and as a solution for administration into the vein. The solution contained a small amount of quizartinib with a radioactive tag. This tag helped researchers track the quizartinib from the solution in the body and distinguish it from the quizartinib tablets.

Main goals of this study

The main question the researchers wanted to answer in this study was:



**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.*

Other goals of this study

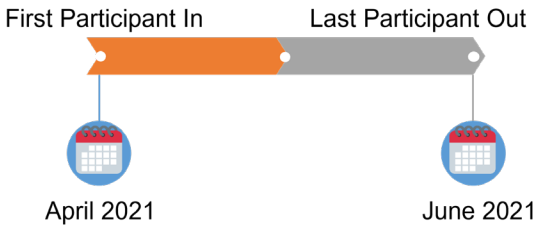
Researchers also wanted to answer the following questions:

- What side effects could the 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 April 2021 and the last participant completed the study in June 2021.

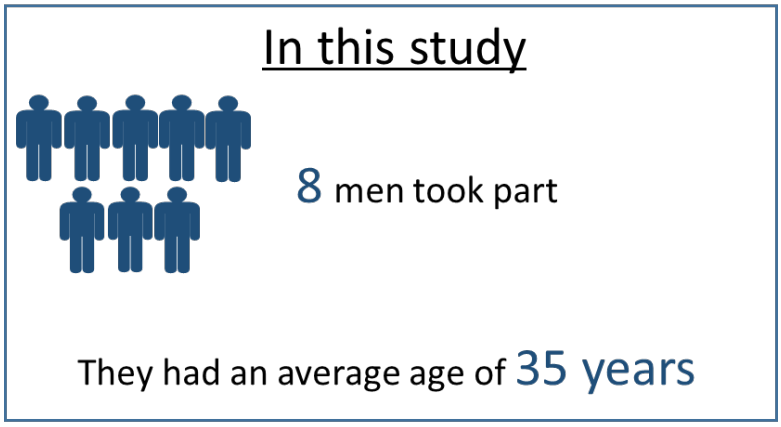
The study was completed as planned and a study report was created. This summary is based on that report.

Who was in this study?

This study included participants from the United Kingdom.

Healthy men could take part in this study if they:

- were 18 to 55 years of age,
- were of average body size and weight,
- were using effective birth control methods during the study or were unable to have children,
- had normal healthy kidneys and liver as measured by different blood tests,
- were willing not to take a shower for 24 hours after taking the study drug.



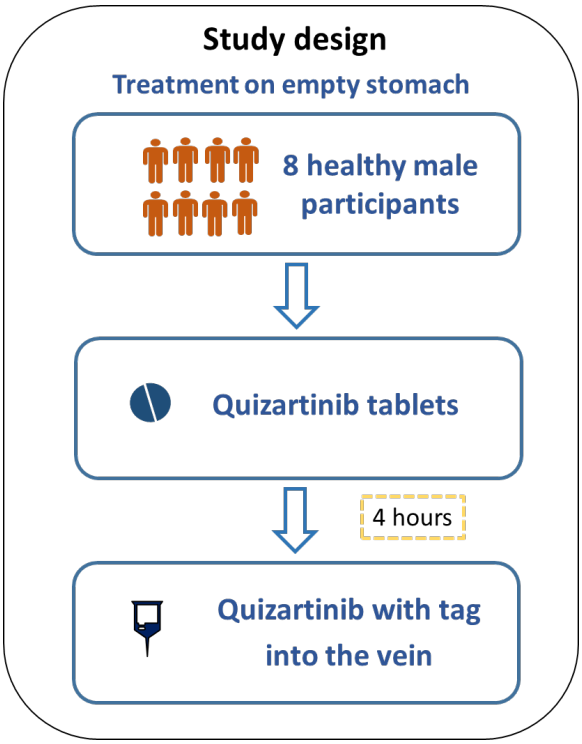
What happened during this study?

This was a Phase 1 study. Phase 1 studies are done to find out the safety of a new study treatment and how it 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 to the participants.

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.

All participants received a single dose of 60 milligrams (mg) quizartinib in tablet form by mouth, on an empty stomach. Four hours later, and still on an empty stomach, participants received 50 micrograms (µg) of quizartinib with a radioactive tag through a needle in a vein.



Researchers took blood, urine and stool samples from participants at defined time points. Participants’ health was monitored throughout the study and they were discharged from the study site on Day 22.

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. A full list of the questions the researchers wanted to answer and a detailed presentation of the results can be found on the websites listed at the end of this summary.

How much quizartinib was available in the plasma of participants when given by mouth compared to administration into the vein?

The amount of quizartinib available in the plasma after participants received quizartinib by mouth was about 71% of the amount available in the plasma after quizartinib was administered into the vein. This means that about 71% of quizartinib reached the bloodstream when given by mouth, as a tablet.

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.

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 during this study. No deaths were reported due to side effects.

How many participants had side effects?

No participants had side effects 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 helped researchers find out the amount of quizartinib that reaches the bloodstream when quizartinib is given by mouth as a tablet.

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.

Where can I learn more about this study?

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

- www.clinicaltrials.gov: Use the NCT identifier NCT04796831 in the search field.
- www.clinicaltrialsregister.eu/ctr-search/search: Use the EudraCT identifier 2021-000198-10 in the search field.

Please remember that the results on these website may be presented in a different way. If you were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study site.

Full study title:
An open label study to determine the absolute oral bioavailability of quizartinib using a radiolabeled microtracer in healthy subjects
AC220-A-U107 (QSC203118)

Sponsor: Daiichi Sankyo, Inc.

Sponsor contact information:
211 Mount Airy Road, Basking Ridge, NJ 07920
Email: CTRInfo@dsi.com
Phone number: 1-908-992-6640

Date of this summary: 14 Mar 2022

This summary was prepared by Kinapse Ltd, a Syneos Health company.