



CLINICAL STUDY RESULTS

A study to compare how the body absorbs different capsule strengths of fidrisertib and how food changes this process in healthy adults

Overall, the results suggest that the different capsule strengths of fidrisertib were absorbed similarly by the body. In addition, food had no meaningful effect on how much fidrisertib was absorbed.

The results shown in this summary represent one clinical study in healthy adults. Other clinical studies may produce different results.

This lay summary was created by Ipsen with the assistance of a third-party writing service provider

What was the study about?

Fidrisertib (also known as IPN60130) is being developed as a treatment for fibrodysplasia ossificans progressiva (FOP).

FOP is a very rare condition in which bone grows in places where it does not normally exist, such as muscles and tissues that hold muscles and bones together (tendons and ligaments). This new bone can cause loss of movement.

Palovarotene is an approved drug for patients with FOP above 8 to 10 years of age. However, as FOP starts to affect the body from early childhood, there is a need for new treatments.

Fidrisertib is expected to act on the abnormal protein that causes extra bone growth in patients with FOP.

Researchers wanted to know if:

- the same dose of fidrisertib taken as different capsule strengths is absorbed similarly by the body. Capsule strength is the amount of medicine inside each capsule.
- taking fidrisertib together with food affects how it is absorbed by the body.

The aims of this study were to:

- compare how the body absorbs different capsule strengths of fidrisertib in healthy adults.
- understand whether eating food changes how fidrisertib gets into the blood of healthy adults.

This study did not test if fidrisertib helps improve FOP.

The study took place between January 2025 and March 2025 at a single study site in the United States.

Who took part in this study?



22

PARTICIPANTS



14

MEN



8

WOMEN



36 YEARS
AVERAGE
AGE

To take part in the study, participants had to:



- be aged between 18 and 64 years,
- be healthy, as assessed by the study doctors,
- weigh at least 45 kilograms (kg), and
- have a body mass index (BMI), a measure of body fat based on height and weight, between 18 and 30 kg per square meter (kg/m²).



Participants could not take part in the study if:

- they had health conditions or had received treatments that could affect the result of the study.

What treatments were used in this study?

Study Treatment

Fidrisertib was taken as capsules by mouth at a dose of 50 milligrams (mg) on Days 1, 9, and 17 as follows:

- Study Treatment A: 5 capsules of 10 mg each on an empty stomach (fasted state)
- Study Treatment B: 1 capsule of 50 mg in the fasted state
- Study Treatment C: 5 capsules of 10 mg each 30 minutes after a meal (fed state).

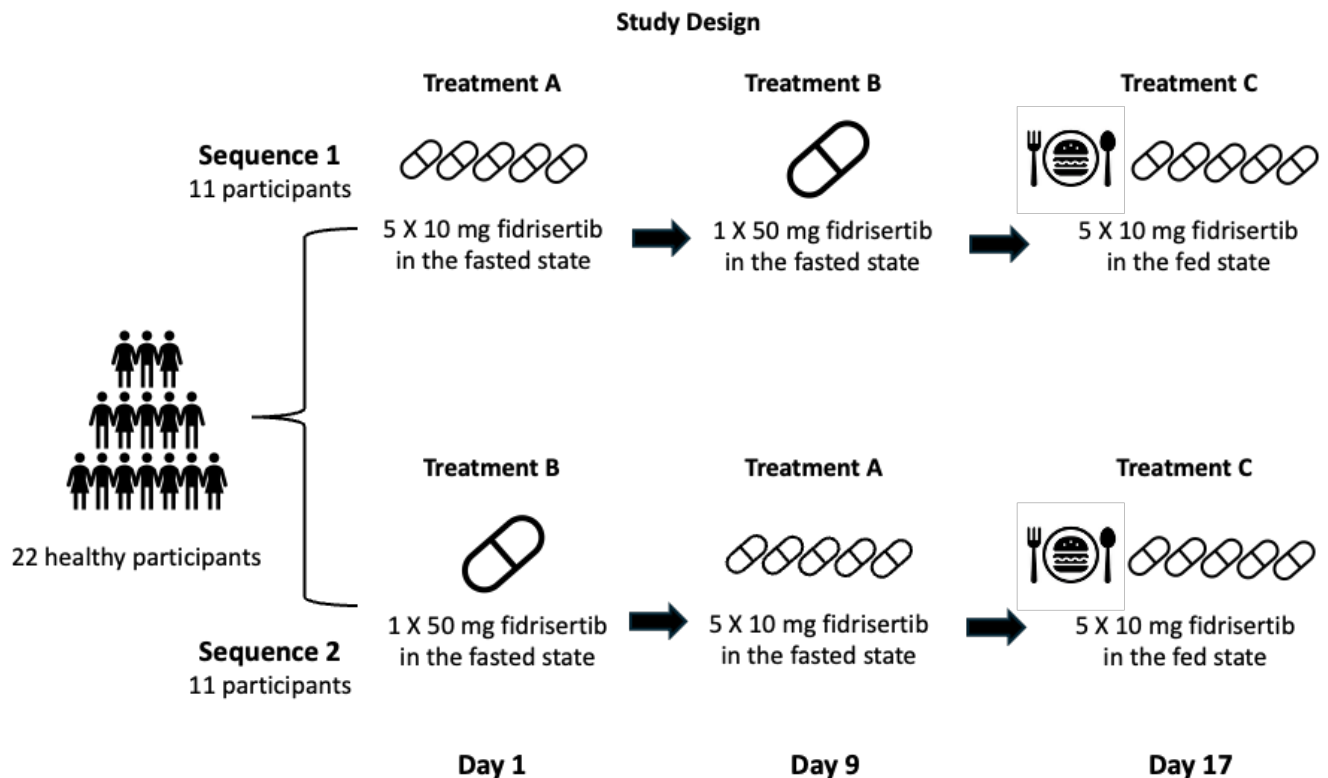
This study had 2 parts:

Screening: The study doctor checked whether participants could take part in this study within 28 days before they started the study treatment.

Treatment:

22 participants were randomly assigned to 1 of 2 sequence groups using a computer system. This process is called randomisation. It means that each participant could be assigned to any of the 2 sequence groups, and it helps to make sure that the participants were divided into groups in a balanced and fair way.

This was a “crossover” study. This means that all participants received all treatments given in the study, but in a different sequence, as shown in the figure on the next page. There were 8 days between each study treatment.



This study was “open-label”. This means that the researchers and the participants knew the sequence of treatments given to each participant.

The participants were admitted to a clinical research hospital 1 day before the first dose of fidrisertib. They were discharged 3 days after the last dose.

The study lasted for up to 7 weeks from the screening visit to the end-of-study visit.

Researchers monitored the health of the study participants during the study.

What did researchers find out in the study?

- The 2 capsule strengths of fidrisertib were absorbed similarly by the body.
- Food had no meaningful effect on the total amount of fidrisertib reaching the blood.

To compare how different capsules strengths of fidrisertib were absorbed by the body and to understand how food changes this process, researchers measured participants' blood levels of fidrisertib at different time points during the study. They looked at the highest and total amounts of fidrisertib in the blood over time to answer the following questions.

Were the amounts of fidrisertib in the blood similar after participants took it as a single 50 mg capsule or 5 capsules of 10 mg?

The highest and total amount of fidrisertib in the blood over time were similar whether the 50 mg dose was given using 10 mg (Study Treatment A) or 50 mg (Study Treatment B) capsule strength. This confirms that the body absorbed both capsule strengths at the same speed and in the same amount.

What was the effect of food on the amount of fidrisertib in the blood?

Researchers found that the highest amount of fidrisertib in the blood was lower when taken in the fed state (Study Treatment C – 5 capsules of 10 mg each) than when taken in the fasted state (Study Treatment A – 5 capsules of 10 mg each). However, researchers found similar amounts of fidrisertib in the blood over time for the 2 study treatments.

This means that eating food had no meaningful effect on the total amount of fidrisertib absorbed by the body.

What were the other findings in the study?

How safe and well-tolerated was fidrisertib in healthy adults?

The researchers found that fidrisertib was safe and well-tolerated by healthy adults in this study, with no differences between the 2 capsule strengths when taking it with or without food.

How did the treatment make participants feel?

During the study, participants were asked to report any 'adverse events', that is, if they felt unwell, experienced any kind of medical event, or noticed anything different about their bodies. Researchers recorded all adverse events reported by participants, whatever the cause. For example, if some participants caught COVID-19, this was reported as an adverse event, although it was not related to the study treatment.

If the study doctor thinks an adverse event may be related to the study treatment, it is called a 'side effect'.

A side effect is considered 'serious' when it is life-threatening, causes lasting problems, or leads to hospitalisation.

- No participants in this study experienced any serious side effects.
- No participants died during the study.

Overall, 18% (4 out of 22) of participants experienced a side effect.

The most commonly reported side effect was headache, which occurred in 14% (3 out of 22) of participants. None of the other side effects occurred in more than 1 participant each.

No participants stopped taking part in the study because of a side effect.

More information

For more information about current treatments available, please speak to your healthcare provider. If you have any questions about this study, please contact the sponsor, Ipsen at:



clinical.trials@ipson.com

Future research

There are more ongoing studies with fidrisertib.

Study identification and other information

FULL STUDY TITLE: A Phase I, Open-Label, Single-Centre, Randomised, 2-Sequence, 3--Period, Crossover Study to Investigate the Relative Bioavailability of Two Fidrisertib Dosage Strengths and the Effect of Food on the Pharmacokinetics of Fidrisertib in Healthy Adult Participants

PROTOCOL: CLIN-60130-456

OTHER INFORMATION: Phase I studies are conducted with small numbers of healthy participants. This helps researchers figure out what dose to use in future studies, to understand what happens to the study drug in the body and how safe it is.



We thank all the volunteers who took part in this study. Without their support, advances in treatments for medical conditions would not be possible.



We would also like to thank the people who took the time to review this document to make it easier for a general audience to read.

