

What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a drug is safe and whether it works. Before a doctor can prescribe a new drug, it must go through several phases of clinical research:



Phase 1: First study of the drug in people (often healthy volunteers)



Phase 2: Study of the drug in people with the condition the drug is for



Phase 3: Study confirming how well the drug works



Phase 4: More research after the drug is approved

The ENLIGHTEN Fibrosis study is a Phase 3 study.

Clinical research studies rely on volunteers. Taking part in the study is your choice. The rules and ethics that doctors must follow to practice medicine also apply to clinical research studies.

ENlighten fibrosis



To learn more, scan to visit enlightenclinicalstudy.com today!

To talk to an ENLIGHTEN Fibrosis study team member, contact:



Are you overweight? Do you have...

- high blood pressure?
- high triglycerides?
- high blood sugar?
- fatty liver disease?

If so, you may also have a type of liver disorder called MASH (formerly known as NASH). Learn about MASH and find out if the ENLIGHTEN Fibrosis study is right for you.

What is MASH?

MASH stands for *metabolic dysfunction-associated steatohepatitis*. It used to be called NASH, or nonalcoholic steatohepatitis. MASH is caused by having too much fat in the liver. It is normal for the liver to have some fat, but too much fat can cause harmful damage like liver scarring (fibrosis). If fat continues to build up, it can lead to extreme scarring (cirrhosis) or liver failure.

Stages of liver damage



Healthy liver



Fatty liver



Scarring (fibrosis) ——— MASH



Extreme scarring (cirrhosis)

What is the ENLIGHTEN Fibrosis study?

The ENLIGHTEN Fibrosis study is a clinical research study for adults with MASH. The goal of the study is to find out if the study drug can reduce the harmful effects of MASH, including liver scarring.



What is the study drug?

The drug being researched in this study is called pegozafermin (peh-go-zah-fur-min). Researchers think pegozafermin may help the body process and store fats better so less fat builds up in the liver. Pegozafermin is **investigational**. This means it is not approved by any health or regulatory agencies. It can only be used in clinical research.

If you join the study, you will be assigned at random to a group that receives pegozafermin or to a group that receives placebo. Placebo looks like pegozafermin but has no active drug, so researchers can compare results across groups.



You will have a 2 in 3 chance of being assigned to pegozafermin, but you will not know your assignment.

Both pegozafermin and placebo are called the study drug.

Who can join the study?

You may be able to join the study if you meet these criteria:

- 18 to 75 years old
- Diagnosed with MASH and liver scarring (fibrosis)

If you do not know whether you have MASH or liver scarring, the study doctor can help you find out.

What can study participants expect?



Screening period

(about 12 weeks)

- Visit the study clinic several times for study health checks to find out if you qualify.
- Have a liver biopsy if you have not had one in the 6 months before Screening.



Study drug period

(about 3 years)

- Receive weekly or bi-weekly (every 2 weeks) injections of the study drug.
- Injections are given under the skin of your belly area.
- A nurse gives the first injections at the study clinic. Then, you or a caregiver can be trained to give injections at home.
- Have study health checks about every 2 to 3 months for the first year, then alternate phone calls and visits every 3 months for 2 more years.
- Follow instructions for diet, activity level, and alcohol use throughout the study.



Follow-up period

(3 weeks)

- Visit the study clinic for study health checks 3 weeks after you stop taking the study drug.