

What is the STARLIGHT Study?

STARLIGHT is a clinical study testing the effects of the study drug, GSK4532990, in adults 18 to 65 years of age with alcohol-related liver disease (ALD). Researchers want to see if the study drug can improve ALD and if it's safe and well-tolerated.

In ALD, damage to the liver caused by heavy alcohol use worsens over time. The study drug works by reducing the levels of a certain protein in the liver that may be involved in the development and worsening of ALD. This may reduce the harmful effects of alcohol on the liver.

What are clinical studies?

Clinical studies are done to learn more about how the body responds to a certain study drug and whether that drug works for a specific disease or medical condition.

Thank you for joining the STARLIGHT Study.

You may or may not directly benefit from being in this study, but your participation is highly valuable. Information learned from this study may help others with ALD in the future.

Being in a clinical study is voluntary. If you decide to join and then change your mind, you can leave at any time.

For more information about the STARLIGHT Study, visit starlightgsk.com and contact:



We are here to answer any questions you have!

PIN: 2291

STARLIGHT-MF-V2-EnP

The STARLIGHT Study

A clinical study for adults with alcohol-related liver disease

Study Overview



What happens during the study?

You will be in the study for about 16.5 months (70 weeks).

SCREENING (up to 4 weeks)

Once you agree to participate by signing the Informed Consent Form, the study doctor will collect information about your health and run tests to make sure you qualify for the study.

STUDY TREATMENT (up to 48 weeks)

If you qualify for the study, you will have visits to receive the study treatment and have health checks and tests. Some visits may take place at your home.

FOLLOW-UP (18 weeks)

After completing the study treatment, you will have a few more visits to check on your health.

What study treatment will I receive?

If you qualify for the study, you will be placed by chance into a group to receive:

- The study drug GSK4532990 (active drug)
or
- A placebo (inactive drug)

The placebo looks just like the study drug but contains no active medicine. This helps researchers understand the true effects of GSK4532990. Neither you nor the study doctor will know if you are receiving the study drug or the placebo. This helps to keep the study fair.

Stopping alcohol use is recommended for people living with liver disease. However, this may not always be possible. You will still be able to participate in this study even if you have not stopped drinking.

How will I receive the study treatment?

The study treatment (the study drug or the placebo) is given as an injection (shot) into the skin. Each dose is given as 2 injections.

You will receive a dose of the study treatment every 4 weeks for 48 weeks (11 months).

What tests will I have at study visits?

During the study, you will have up to 22 visits. It's important to attend all scheduled visits to check on your health and to see how the study treatment may be affecting you.

Inside this brochure is a summary of tests that you may have at these visits. Speak with the study doctor to learn more.



Summary of study visits and tests

Below is a summary of visits and tests that you will have during the study. You will not have every test at each visit. Most visits will last a few hours, so you may need to plan ahead. You may be asked to fast (not eat or drink anything but water) for 10 hours before certain visits.

Screening

(up to 4 weeks; 2 visits)

You will have 2 visits within 4 weeks of starting the study.

Study Treatment

(up to 48 weeks; up to 17 visits)

During the first month, you will have 6 visits, and then you will have visits about every 4 weeks to receive the study treatment and have tests.

Follow-up

(18 weeks; 3 visits)

You will have visits at Week 52, 60, and 66.

Health information



Medical history



Medicine review

Optional tests



Spleen imaging



Liver biopsy



Additional blood tests
(including DNA)



Liver stiffness
imaging

Health checks and tests



Physical exam



Height/Weight



Vital signs



Heart activity
(ECG)



Liver imaging



Blood tests
(including DNA)



Urine test



Pregnancy test



Hair sample
testing



Injection site reaction check



Questionnaires

You will not have every test at each visit.

ECG = electrocardiogram.

Glossary



Blood tests (including DNA): Blood samples will be taken from your vein, usually in the arm, to check your overall health, to see how your liver is working, and to check for drug or alcohol use. Your blood will also be tested for certain genes that have been linked to liver disease.



Hair sample testing: Two small samples of hair from the top of your head will be cut and tested for drug or alcohol use.



Heart activity: The electrical activity of your heart is measured using a painless test called an electrocardiogram (ECG). For this test, you will lie down, and small sticky pads will be attached to your skin. The pads are connected by wires to a computer that picks up signals every time your heart beats.



Height: The study doctor or nurse will measure how tall you are.



Injection site reaction check: The area of skin where the study drug was injected will be checked for swelling or redness.



Liver biopsy (optional): This test is optional and may not be available at all study sites. For the procedure, small pieces of your liver would be removed using a special needle that is passed through the skin of your abdomen. You will be given medicine to numb the area and reduce pain. The samples will then be tested in a lab.



Liver imaging: This test uses a type of ultrasound called a FibroScan® to look at your liver and how it may be responding to treatment. During the test, you will lie on your back and have a wand placed on your abdomen. You will be asked to fast (not eat or drink anything except water) for 3 hours before this test.



Liver stiffness imaging (optional): This test is optional and may not be available at your site. You would have a scan of your liver to better understand your liver disease and to see how it responds to treatment. This test combines a magnetic resonance imaging (MRI) scan with vibrations to get detailed stiffness images of the inside of your body. You would lie on your back inside a large, round scanning tube. You would need to fast (not eat or drink anything except water) for 4 hours before the test.



Medical history: You will answer questions about your health, including any illnesses or hospital stays due to liver disease that you may have or have had in the past. The study doctor will also advise you on your alcohol use.



Medicine review: The doctor will ask questions about medicines you are taking now or have taken in the past.



Physical exam: The study doctor will check your overall health by examining different parts of your body and listening to your heart and lungs.



Pregnancy test: Participants who can become pregnant will have their blood or urine tested for pregnancy.



Questionnaires: You will use an app on a digital device to answer questions about your drinking habits as well as questions about how liver disease affects your quality of life. You will answer questions about your symptoms, energy levels, mood, physical activity, sleep, and social activity.



Spleen imaging (optional): This test is optional and may not be available at your site. The test is similar to the liver imaging test (FibroScan), but the wand will be moved on the side of your abdomen opposite your liver in order to examine your spleen.



Urine test: A sample of your urine will be tested to check your general health and to see how your liver and kidneys are working. Your urine will also be checked for drug or alcohol use.



Vital signs: These measurements include body temperature, heart rate (how fast your heart beats), breathing rate (how many breaths you take in 1 minute), and blood pressure (how your heart is pumping).



Weight: The study doctor or nurse will measure how much you weigh.

