Statins for the Treatment of NASH (STAT NASH)

NCT04679376

July 22, 2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 22, 2025**
Not to be used after: **January 2, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: STAT-NASH Trial "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of Statins in Adult Patients with Non-Alcoholic Steatohepatitis (NASH)"

IRB#: 22-007824

Principal Investigator: Dr Manal Abdelmalek and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research study is to determine whether atorvastatin ("statin"), is safe and effective in the treatment of non-alcoholic steatohepatitis (NASH). NASH is inflammation of the liver due to a fatty liver. In some people, NASH can lead to scarring of the liver (fibrosis) and over time, increased scarring of the liver can result in cirrhosis. In some, but not all patients, cirrhosis of the liver can lead to liver failure, liver cancer or need for liver transplant. You have been asked to take part in this research because you have been diagnosed with NASH.
What's Involved	The study will last up to 100 weeks (26 months). During this time, you will be required to have a study visit at the clinic approximately once every 3 months. In order to see if you are eligible to take part in the study, tests will be done to see if you qualify.

	These tests can be done at any time but must be completed within a period of 8 weeks (the screening period). If you are eligible to take part in the study, you may receive the study drug for 96 weeks (24 months). You will be monitored up to 28 days (4 week) after you stop the study drug. Tests will include blood draws, liver biopsies, pregnancy testing, a fibroscan, and medication and adverse event assessments. This study involves a placebo; there is a 50 percent chance that you will receive the placebo instead of atorvastatin.
Key Information	The risks, benefits and alternatives to participating in this study are described in this document. Atorvastatin is FDA approved for treatment of high cholesterol and prevention of cardiovascular diseases but not for NASH. The most common side effects of atorvastatin (occurring in 5% of people taking statins) are muscle pain. If you are interested in learning more about this research study, please continue to read below. The study staff or doctor will answer all your questions.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Manal Abdelmalek, MD **Phone:** (507) 266-8202 **Study Team Contact:** Christopher Kigongo (507) 266 1998 Eliabe Abreu (507) 284-0620 **Institution Name and Address:** Mayo Clinic Institutional Review Board 200 1st Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you may have nonalcoholic steatohepatitis (NASH).

Why is this research study being done?

The purpose of this research study is to determine whether the study drug, atorvastatin (Lipitor®), is safe and effective in improving the features of NASH.

Atorvastatin, the drug used in this study, was approved for clinical use in 2001 by the U.S. Food and Drug Administration (US FDA) for the treatment of high cholesterol and to decrease risk of cardiovascular disease due to its ability to decrease total cholesterol, decrease LDL ("bad") cholesterol and increase HDL ("good") cholesterol. However, atorvastatin has not been approved to treat NASH, and therefore using it in this study is considered investigational. The word "investigational" means the drug is still being tested, as it has not been approved by the FDA for this indication. Atorvastatin is best used combination with a healthy diet and lifestyle.

Information you should know

Who is Funding the Study?
This study is funded by a research grant from the United States Department of Defense (DoD). The DoD will pay Mayo clinic to perform this research.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

Your participation in the study is expected to last for approximately 108 weeks.

What will happen to you while you are in this research study?

This study consists of 3 periods which span a total duration of approximately 108 weeks (26 month)

- Screening Period (8 weeks)
- Study Drug Period (96 weeks)
- Follow-up Period (4 weeks)

To be eligible for this study, you must be at least 18 years old and have had a liver biopsy as part of your routine medical care during the last 90 days that shows you have NASH. If you have not had a liver biopsy as routine medical care during the last 90 days and want to participate in this study, you may choose to have a biopsy for research purposes. This biopsy will be paid for by the research study.

You will not be allowed to join this study if you have cirrhosis or if you have had significant amounts of alcohol to drink within the past year. We will ask you questions to check if you are drinking significant amounts of alcohol during the study.

If you are a woman capable of becoming pregnant, you must agree to use effective birth control methods during the study. Women who are nursing an infant may not enroll in the study. If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Physical exam and medical history
- Fibroscan (liver stiffness and fat measure)
- Liver biopsy (if not done within the last 90 days)
- Blood tests, if they have not otherwise been done as part of your clinical care at Mayo.

You must also be willing to swallow one capsule each day for 96 weeks (2 years).

Screening Procedures

Visit 1: Screening Visit: If you agree to participate in the study by signing and dating this consent form, Dr. Abdelmalek and her study team will have up to 8 weeks to see if you qualify. This is called "screening". Screening you for the study will involve completing some procedures and tests, including but not limited to taking some blood and urine samples. The screening activities will include the following:

- You must come to this visit **FASTING (**noting to eat or drink, except water to take your routine medication).
- A complete history will be recorded including the medications you are taking.
- You will have a physical exam, including measurement of your height, weight, waist circumference, and vital signs (temperature, pulse rate, breathing rate, and blood pressure).
- Blood will be drawn for routine tests used to evaluated patients with NASH, including tests to measure liver and kidney function. If such blood tests have been done within the past 90 days, the results will be reviewed and used for screening.
- If you are a woman of childbearing potential, urine will be obtained for a pregnancy test. If you are a woman of non-childbearing potential, blood may be drawn to confirm levels of a reproductive hormone in your body (about half a teaspoon)
- If you have not had a liver biopsy in the past 90 days before enrolling in this study, a liver biopsy may be performed to ensure that you have NASH with at least a moderate level (at least stage 2) of fibrosis.

Dr. Abdelmalek will review your screening tests and/or the available results of recent testing to confirm that you are eligible to participate in this study. If you are eligible, you will be scheduled for a randomization visit to being the study drug phase of this study.

Study Drug Phase:

Visit 2: Randomization Visit (Day 1): On Day 1, you will be randomly assigned to one of two groups. This is known as the randomization visit. You will have an equal chance of receiving one of the following:

a) Placebo ("dummy pill" with no active medicine inside)
b) Atorvastatin 40 mg tablet

Neither you nor Dr. Abdelmalek or her staff, will know if you are receiving the study drug or a placebo (this is called a double-blind study). However, the identity of the drug you were randomized to can be made available in the event of a medical emergency. Dr. Abdelmalek will let you know if you received the study drug or the placebo after the study is completed. You will be asked to keep a daily diary of the day and time you take the study drug.

You must come to this visit **FASTING** (nothing to eat or drink for 8 hours, except water to take your routine medication). The following tests will be conducted:

- Research staff will review your medical history, medications and any symptoms you have.
- Your vital signs and weight will be obtained
- You will be asked to complete an alcohol use and quality of life questionnaires.
- You will be randomly assigned to receive the study drug or placebo.
- About 3 tablespoons of blood will be drawn for routine tests if such tests have not otherwise recently been done for your standard of care. These tests will include a lipid panel, glucose, insulin level, liver function and blood pregnancy (if you are a woman of childbearing potential)
- A Fibroscan to measure your liver stiffness and fat quantity will be obtained. Liver stiffness (how hard the liver is) can be measured using a sound wave machine (a Fibroscan). Gel is applied to your skin and a trained technician presses a small, hand-held device, about the size of a bar of soap, against your skin over the area of the liver (upper right side of the belly), moving it as necessary to capture an image.

On Day 1, after all tests and procedures have been performed, you will be given a 4-week supply of study drug. Each morning, at approximately the same time, you will take ½ tablet (20 mg daily) every morning for the first 2 weeks to ensure that you can tolerate the study drug. The study drug does not need to be taken with food. You will also be given a diary to record when you take the study drug every day at home.

Visit 3 (Week 2) Telephone Call

The study coordinator will call you and talk with you about any symptoms or side effects since starting the study drug. If you are tolerating the study drug, you will be asked to take 1 tablet by mouth daily.

Visit 4: Week 4 (within ± 4 days)

During the Week 4 visit the following will be done during this visit:

- Verify the study drug was administered correctly
- Dispense study medication supply
- Record vital signs and weight
- Counsel you on weight loss, diet and exercise
- Record any symptoms you may have.
- Record all medications that you have taken since your prior visit
- You will receive counseling on a healthy lifestyle
- Obtain a urine pregnancy test for women of childbearing potential

Visits 5, 7, 9, and 11 (Weeks 12, 36, 60 and 84 ± 4 days)

You do not need to be fasting for these visits. The following will be done during these visits:

- Verify the study drug was administered correctly with a pill count
- Dispense study medication supply
- Record vital signs and weight
- Counsel you on weight loss, diet and exercise
- Record any symptoms you may have
- Record all medications that you have taken since prior visit
- You will receive counseling on a healthy lifestyle
- Obtain a urine pregnancy test for women of childbearing potential

Visit 6 and 10 (Week 24 and 72 ± 4 days):

You must come to this visit **FASTING (**noting to eat or drink for 8 hours, except water to take your routine medication). The following tests will be conducted:

- Research staff will review your medical history, medications and any symptoms you have.
- Verify the study drug was administered correctly with a pill count
- Dispense study medication supply
- A physical examination, vital signs height and weight will be obtained
- About 3 tablespoons of blood will be drawn for routine tests, if such tests have not otherwise been done for your routine clinical care. These tests will include a lipid panel, glucose, insulin level, and liver function
- You will receive counseling on a healthy lifestyle
- A urine pregnancy (if you are a woman of childbearing potential)
- You will be asked to complete an alcohol use questionnaire
- A Fibroscan to measure your liver stiffness and fat quantity will be obtained.

Visit 8 (Week 48 ± 4 days):

You must come to this visit **FASTING (**noting to eat or drink, except water to take your routine medication). The following tests will be conducted:

- Research staff will review your medical history, medications and any symptoms you have.
- Verify the study drug was administered correctly with a pill count
- Dispense study medication supply
- A physical examination, vital signs height and weight will be obtained
- About 3 tablespoons of blood will be drawn for routine tests, if such tests have not otherwise been done in the past few days for your standard of care. These tests will include lipid panel, glucose, insulin level, and liver function.
- You will be asked to complete an alcohol use and quality of life questionnaires.

- You will receive counseling on a healthy lifestyle
- A urine pregnancy (if you are a woman of childbearing potential)
- You will be asked to complete an alcohol use questionnaire
- A Fibroscan to measure your liver stiffness and fat quantity will be obtained

Visit 12: End of Study Regimen Visit (Week 100 ± 4 days)
If you stop the study early, you will be asked to complete an "End of Study Regimen" visit. Otherwise, this visit is done at the end of the study phase and is visit when you stop taking the study drug.

You must come to this visit **FASTING (**nothing to eat or drink for 8 hours, except water to take your routine medication for 8 hours before this visit). The following tests will be conducted:

- Research staff will review your medical history, medications and any symptoms you have.
- Verity the study drug was administered correctly with a pill count
- A physical examination, vital signs height and weight will be obtained
- About 3 tablespoons of blood will be drawn for routine tests, if such tests have not otherwise been done in the past few days as part of our clinical care. These tests will include lipid panel, glucose, insulin level, and liver function
- You will be asked to complete an alcohol use and quality of life questionnaire.
- You will receive counseling on a healthy lifestyle
- A urine pregnancy (if you are a woman of childbearing potential)
- You will be asked to complete an alcohol use and quality-of-life questionnaires
- A Fibroscan to measure your liver stiffness and fat quantity will be obtained
- A liver biopsy will be performed.

Visit 13: Follow-up Visit (Week 112 ± 4 days)
This is your last visit for the study. The study staff see how you are doing and lend guidance on continued care and medical follow-up with your primary care doctor or liver specialist. You must come to this visit **FASTING** (noting to eat or drink, except water to take your routine medication for 8 hours before this visit). The following tests will be conducted:

- Research staff will review your medical history, medications and any symptoms you have since stopping the study drug.
- Vital signs height and weight will be obtained
- About 3 tablespoons of blood will be drawn for routine tests, if such tests have not otherwise been done in the past few days as part of our clinical care. These tests will include a comprehensive metabolic panel and liver function

Early Termination Visit
If you stop the study early, you will be asked to complete an "End of Study Regimen" visit.

Approval Date: **July 22, 2025**
Not to be used after: **January 2, 2026**

You must come to this visit **FASTING (**noting to eat or drink for 8 hours, except water to take your routine medication for 8 hours before this visit). The following tests will be conducted:

- Research staff will review your medical history, medications and any symptoms you have.
- Verity the study drug was administered correctly with a pill count
- A physical examination, vital signs height and weight will be obtained
- About 3 tablespoons of blood will be drawn for routine tests, lipid panel, glucose, insulin level, and liver function if such tests have not otherwise been performed as part of your clinical care within the past few days.
- You will be asked to complete an alcohol use and quality of life questionnaire.
- You will receive counseling on a healthy lifestyle
- A urine pregnancy (if you are a woman of childbearing potential)
- You will be asked to complete an alcohol use questionnaire
- A Fibroscan to measure your liver stiffness and fat quantity will be obtained
- A liver biopsy will be performed.

Unscheduled Visits

In addition to the regular study visits, an unscheduled visit might be necessary to repeat blood tests, perform a safety check if required by Dr. Abdelmalek. Dr. Abdelmalek or her study team will inform you if you need to come into the clinic for an unscheduled visit during the study.

If you decide to stop participating in the study, we encourage you to talk to your doctor first. You will be asked to continue with all study visits and procedures, and in particular, agree to safety monitoring and the collection of clinical outcomes information for the duration of the study. In the event that you do not want to attend study visits but are willing to provide health information then you agree to be contacted by letter, telephone, or other means of communication to provide important information on your health status. If this is the case, the study team may also review your medical chart after your withdrawal from the study to obtain information about your medical course or laboratory results. If you do not agree to further data collection, we will not access your record for more information after withdrawal.

Dr. Abdelmalek or her study team may use any labs results which are in your medical record for research purposes, if such labs have otherwise been performed as part of your care at Mayo Clinic. Blood test results in your medical record or tests which will otherwise be done by your physician as part of your standard of care (SOC) may be used for research. Any tests which not done as part of your standard of care, but required for research, will be done on study.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research.

Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

If you have previously treated with any statin drug and were intolerant to the medication, please inform Dr. Abdelmalek or her staff.

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with Dr. Abdelmalek and your regular health care provider if you choose.

Uncommon side effects include:

- Indigestion symptoms (nausea, loss of appetite, abdominal discomfort
- Increased muscle enzymes (creatinine kinase), muscle aches or spasm
- Chest pain
- Joint pain
- Insomnia
- Memory or cognitive impairment

You will be monitored for the duration of your time in the study and you should tell Dr. Abdelmalek about any changes in your health while taking part in the study.

Rare Allergic Reactions:
In addition to the risks listed above, there may be unknown, infrequent, and unforeseeable risks associated with the use of the study drug, including severe or life-threatening allergic reactions or unexpected interactions with another medication. Symptoms of an allergic reaction may include rash, flushing, itching, rash, lightheadedness, fainting, or very rarely, severe rash affecting skin and mucous membranes such as mouth, rhabdomyolysis (breakdown of muscle tissue) with risk of kidney failure

If you have any known allergy to a statin drug, please inform Dr. Abdelmalek or study staff.

Drug and Food Interactions:
For your safety, you must tell Dr. Abdelmalek and the study team about all the prescribed medical foods and drugs, herbal products, over the counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are in the study.

Risks of Drawing Blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising, infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Fasting Risks:
Fasting for 8 hours in preparation for certain blood testing procedures could rarely cause dizziness, headache, stomach discomfort or fainting.

Liver Stiffness Measure (Fibroscan) Risks:
There are no known risks to having a Fibroscan of the liver. Rarely, this test may be associated with a little soreness or small bruise from pressing on the skin with the device.

Risks of Liver Biopsy:
Liver biopsy is a common procedure in which a special needle is used to remove a very small portion of liver. Microscope slides will be made from this piece of liver tissue. The slides will be examined under a microscope by the study doctors to diagnose or to determine the severity of liver disease. A portion of the liver tissue may also be stored for future studies.

In the STAT-NASH Trial, you will have up to two liver biopsies: one at the start (either as part of routine care if this is otherwise scheduled to be done for evaluation of her liver disease or will be performed for research purposes if you have no clinical indication for a liver biopsy), and one when the study drug is stopped. This second biopsy is being done solely for research purposes. The biopsy needle is inserted into the liver through your skin under local anesthesia. Liver specialists from the study, radiologists, or their trainees (under direct supervision) will perform your liver biopsy. They may or may not use ultrasound to guide the biopsy. A small bruise and tenderness at the liver biopsy site is common. About 20% of people have some degree of mild or moderate abdominal pain after a liver biopsy. The pain may last anywhere from a few minutes up to several hours. Pain medication may be required to treat any discomfort you experience. Severe pain from bile leak is rare (<1% of patients). The pain usually disappears within the time of our recover (1-2 hours). Rarely, discomfort may persist for day or two days after the procedure. Very rare complications (< 1:10,000) of a liver biopsy include bleeding, injury to another organ, or infection. Such complications may require hospitalization for observation, and in some circumstances, need for blood transfusion or surgery.

Questionnaires:
Completing the questionnaires could make you feel uncomfortable or upset. You should tell the study staff if you feel uncomfortable or upset while filling out a questionnaire. You have the right to refuse to answer any of the questions.

Reproductive Risks:

For Women
In animal studies, statin drugs are associated with an increased risk of birth defects. It is not certain whether statins increase the risk of miscarriage, birth defects, or other bad outcomes of pregnancy. Women are advised not to take statins during pregnancy. Because of these concerns, women who are pregnant, planning to become pregnant, or breastfeeding are not allowed to participate in the study.

If you are a woman who could possibly become pregnant, (you have not completed menopause or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children a blood pregnancy test will be done at screening, and it must be negative in order to enroll in the study. In women 40 years old and older, blood pregnancy tests can give a false positive or indeterminate result, and additional testing may be required to confirm that you are eligible to continue. Additionally, urine pregnancy tests will be performed at all visits, and they must be negative in order to continue.

You and your partner must either agree to completely abstain from vaginal intercourse for the entire 100 weeks (26 months) of study participation, or until 30 days after your last dose of study drug if you stop your participation early, or agree to use an effective method of contraception for the same length of time. These methods include: (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal methods (birth control pills, implants, injections, patches, vaginal rings), or (e) barrier methods (condoms, diaphragm, cervical cap) plus a spermicide. If you are not currently using one of these methods, Dr. Abdelmalek will discuss options with you, given your medical condition, your personal preferences, and the level of effectiveness required by this study. Because no method of birth control is 100% effective, it is important that you notify your study team immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test.

If pregnancy is confirmed, the study team will ask about your health during pregnancy and the outcome of your pregnancy

Unforeseen Risks:
There may be risks, discomforts, drug interactions or side effects that are not yet known and you might have side effects or discomforts that are not listed on this form. Tell the study team right away if you have any problems.

You will also be notified of any significant new findings, which develop during the course of the study that may affect your willingness to participate. You should get immediate medical help, if necessary, and contact Dr. Abdelmalek or staff if you have any side effects during the study.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator, Dr Abdelmalek or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

If you agree to take part in this study, there may be direct medical benefit to you if you are randomized to atorvastatin. However, this is not guaranteed, and your condition may stay the same or get worse. You may not experience any relief or medical benefit, and if you do, it might only be short lived and not persist. If you are assigned to receive placebo, there are no expected benefits to you beyond those of standard of care. We hope that in the future the information learned from this study will benefit other people with NASH.

What alternative do you have if you choose not to participate in this research study?

You do not have to be in the study to get treatment for NASH. Weight loss with diet and exercise has been shown to be helpful in some patients with NASH. You can choose to get treatment for any other conditions related to your NASH from your regular doctor instead of the study drug. Dr. Abdelmalek and her team will discuss with you the risks and benefits of other treatments.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Hematology panel
- Comprehensive metabolic panel
- Hepatic panel
- Prothrombin time
- Lipid panel
- Glycosylated hemoglobin (HbA1c)

- Urinalysis
- Liver biopsy for research
- Atorvastatin / Placebo
- Pregnancy testing
- Fibroscan test

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will not be paid for being in study.

There is a chance that some commercial value may result from the use of your information and/or sample. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

This research may help scientists to better understand:

- The effect of the study drug on liver disease
- Who could benefit from the study drug

The results of the tests done on your blood sample (also called biologic sample) will not be given to you. Information from these tests may be printed in a medical journal or presented at scientific meetings. Only a summary of data from all subjects will be used.

If you decide you no longer want to take part in this future testing of your biologic samples, please contact Dr. Abdelmalek, and your unused samples will be destroyed. Mayo Clinic investigators may continue to use and disclose the results from samples that were tested before you withdrew your consent.

If you decide to no longer take part in the main study or are taken off the main study by Dr. Abdelmalek, the biologic samples and any accompanying sample data you provided for future research will still be kept and may be used for future testing. If you decide you no longer want to take part in this future testing, please contact Dr. Abdelmalek and your unused samples and accompanying data will be destroyed. Mayo Clinic investigators may continue to use and disclose the results from samples that were tested before you withdrew your consent.

For this study, you are being asked to let Mayo Clinic investigators at Rochester MN, to store and use the samples and accompanying data for future testing for up to 10 years after the end of the study.

Identifiers will be removed from identifiable private information or identifiable biospecimens and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject, if this might be a possibility.
If you approve release of your information and/or samples by checking 'yes' below, Mayo Clinic may send the information and/or samples to researchers who request them, but Mayo Clinic will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers.

Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that reidentified information could be used in discriminating ways, and there could be additional unknown risks. We will limit access to information that can identify you and follow data security standards to protect your confidentiality.

Potential Risks and the Genetic Information Non-Discrimination Act (GINA):

There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at Mayo Clinic, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law. The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research.
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Check 'Yes' or 'No' below and initial next to your choice.

I agree to allow my biologic samples to be collected and stored as leftover unused blood samples and accompanying data to be used for future exploratory testing outside of the main study.

☐ Yes ☐ No Please initial here: _____Date: _____

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 22, 2025**
Not to be used after: **January 2, 2026**

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. You and your information will be given a confidential identification number. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form. We store research materials in locked file cabinets. All information is stored on a password protected computer.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private.
However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions. The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

Approval Date: **July 22, 2025**
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How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you.
However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 22, 2025**
Not to be used after: **January 2, 2026**

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

MAYO CLINIC

Name and Clinic Number

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature