Noninvasive Evaluation of Renal Allograft Fibrosis by MRI

NCT04899167

May 17, 2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **May 17, 2023**
Not to be used after: **March 29, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Noninvasive Evaluation of Renal Allograft Fibrosis by MRI

IRB#: 19-008333

Principal Investigator: Lilach Lerman, M.D., Ph.D. 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 is to gather information on the effectiveness of using imaging tools to monitor the extent of renal fibrosis (scarring) noninvasively. We also aim to determine whether this test is reproducible when done on two different MRI machines. This tool may help decrease the cost and potential complications associated with repeated biopsies, which is currently the way to monitor the progress of fibrosis. You have been asked to take part in this research because you have been scheduled for a follow up renal biopsy after kidney transplantation.
What's Involved	You will undergo two MRI scans on different machines (3.0 Tesla and 1.5 Tesla). One of the MRI scans will take about an hour and the other about 15 minutes. If possible, we will schedule them on the same day.

	During your routine blood draw prior to your biopsy, you will have an extra 10 ccs of blood drawn specifically for research purposes. During your routine biopsy appointment, two additional tissue samples will be taken. Your medical record will be reviewed periodically for the next two years or more, so that we can follow your progress and compare data.
Key Information	The risks associated with study participation are described later in this form, be sure to review them carefully. Risks include pain or discomfort at the site of blood draw, feelings of claustrophobia while inside the MRI machine, and/or pain or bruising at the biopsy site. 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. The goal of the study is to better understand if renal fibrosis (scarring) can be effectively monitored using noninvasive imaging methods. There will not be any direct benefit to you. You will not need to pay for tests and procedures specifically conducted for the research. Your insurance or you will be billed for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.
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. Taking part in this study is completely voluntary and you do not have to participate.

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 a copy of this form to keep. A copy of this form will be put in your medical record.

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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.

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:** Lilach Lerman, MD, PhD **Phone:** (507) 266-9376 **Study Team Contact:** Department of Medicine - Research Hub **Phone:** (507)266-1944 **Institution Name and Address:** Mayo Clinic 200 First St. 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

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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 participate in this study because you have been a recipient of a kidney transplant for end stage kidney disease 4 or more years previously and will be scheduled for a routine checkup and protocol biopsy.

Why is this research study being done?

Developing adequate noninvasive strategies to detect and quantify renal fibrosis (scarring due to deposition of macromolecules) presents a major challenge for healthcare professionals. We will test the hypothesis that quantitative magnetization transfer imaging (a type of MRI) would detect and shed light on the development of renal fibrosis in human recipients of kidney transplantation.

Information you should know

Who is Funding the Study?
The National Institute on Aging.

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?

You will come into Mayo Clinic for one or two study visits, depending on MRI scanner availability. Your medical records will be used in the study for 2 years or more, so that we can follow your progress and compare data.

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

First you will meet with a member of the study team to review the study and this consent form. If you agree to be in this study, you will undergo two MRI scans on different machines (3.0 Tesla and 1.5 Tesla). One of the MRI scans will take about an hour and the other about 15 minutes. If possible, we will schedule them on the same day.

During your routine blood draw, an extra 10ccs of blood will be drawn to determine relevant laboratory values. During your routine biopsy appointment, two additional tissue samples will be taken.

Your medical record will be reviewed periodically for the next two years or more, so that we can follow your progress and compare data.

This study excludes pregnant women; if you think you are pregnant or plan to become pregnant over the course of this study please inform the study staff. If needed, a pregnancy test will be administered prior to the MRI studies to determine pregnancy status.

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.
Residual specimen collected under the IRB protocol15-006003, 'Transplant Clinical Residual Specimen Biobank', might be utilized for the current research study, if for some reason the blood required as per study visits was not successfully obtained.

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

There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study. Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If you feel too confined in the MRI scanner you can inform the technologist and the MRI scan will be stopped. The MRI machine makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

You will also be asked to hold your breath while in the MRI scanner. If you become lightheaded or dizzy, please inform the technologist and the MRI scan will be stopped.

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

The risks of the research biopsies are the same as those for the clinical biopsy. However, the risk increases with each additional biopsy. There is a possibility of soreness, bruising, minor bleeding or even an infection at the biopsy site.

The risk of infection from the biopsy is low, however, you should contact a member of the study team if you develop signs of infection which include:

- Redness
- A hot feeling at the sight of the biopsy
- Swelling

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, 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. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

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

The goal of the study is to gather information; you will not directly benefit from participation. Others with Renal Fibrosis may benefit in the future from what we learn in this research study.

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

This study is only being done to gather information. You may choose not to take part in this study.

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:

- MRI scans
- Biopsies done for research purposes
- Pregnancy test
- Research-related blood test (extra 10 ccs drawn at routine blood draw)
- Renal clearance test (if not part of your routine care)

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. You will also be responsible for any co-payments and deductibles.

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

You will receive $150 for the study visit.

We will pay for your parking in Mayo Clinic facilities during study visits. In order to receive reimbursement, you must provide a copy of the original receipts for those expenses.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you.

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For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

We would like to keep your sample for future research. You can still take part in this current study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Other researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your RNA or DNA, which is the genetic information you inherited from your parents (genetic testing). The Principal Investigator may contact you if there are findings that may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of Renal Fibrosis at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

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. Your research materials will be stored in a locked area within locked cabinets where access to the data is limited to only people involved with this study. If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

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.

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.

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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
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
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.

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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