A Study to Evaluate Microvessel Ultrasound Imaging of Wound Healing in Patients With Chronic Ulcers

NCT05739149

December 11, 2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **December 11, 2024**
Not to be used after: **December 10, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Microvessel Ultrasound Imaging of the Skin and Subcutaneous Tissues to Evaluate Wound Healing in Patients With Chronic Ulcers.

IRB#: 21-012021

Principal Investigator: Dr. Michael Moynagh 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 explore the use of high-resolution microvessel ultrasound imaging system to look for scarring and to monitor healing of your wound and to see if treatment affects the amount of tiny vessels and circulation around the wound. You have been asked to take part in this research because you have a non-healing ulcer and are currently being seen for wound care and treatment.
What's Involved	Study participation involves three study visits. Each visit will last approximately 2 hours during which ultrasound imaging will be performed. You will be asked to undergo two research biopsies during your second study visit.

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Key Information	The risks associated with study participation are completely described later in this form, be sure to review them carefully. The goal of the study is to gather information; you will not directly benefit from participation. There is no costs to you for being in the study.
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 either a printed or electronic copy of this form to keep.

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(s):** Michael Moynagh, M.D. **Phone:** (507) 284-8317 **Study Team Contact:** Rica Pol **Phone**: (507) (507) 422 5118 **Institution Name and Address:** Mayo clinic 200 First 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 because you have a lower extremity non-healing ulcer and are currently being seen for wound care and treatment.

The plan is to have about 10 people take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research is to explore the use of high-resolution microvessel ultrasound imaging system to look for scarring and to monitor healing of your wound and to see if treatment affects the amount of tiny vessels and circulation around the wound.

Information you should know

Who is Funding the Study?
Mayo Clinic is funding the majority of this study. We have also received some funds from American Federation for Aging Research to support the biopsy testing and 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.

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the Financial Conflict of Interest for one or more of the

investigators and/or Mayo Clinic related to this research and they have determined that this Financial Conflict of Interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

- Additional information is available to any interested study participant regarding the details of this Financial Conflict of Interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.
- One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

You will be in this research study for approximately 3 months.

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

This research will take you three study visits to complete including your standard of care wound treatments along with research ultrasounds and biopsies.

Visit 1
A member of the study team will meet with you to review the consent form and answer any questions. If you choose to sign the consent form, the study coordinator will schedule all research related procedures on your behalf.

As part of your standard of care visit you will have your wound care performed. A photo of your ulcer will be taken with a measuring grid as part of this visit. All identifying features will be redacted from the photos. The study team will use this information to plan for the biopsies at Visit 2.

As part of the study a urine pregnancy test is required prior to each ultrasound visit for all women who are able to become pregnant. You will be told the results of the pregnancy test. If the pregnancy test is positive, you will not be able to continue to take part in the study.

Visit 2 (3 week)
As part of your standard of care you will have your wound care performed and a photo of your ulcer will be taken with a measuring grid. During this appointment you will undergo a research ultrasound examination and two skin biopsies.

For the ultrasound examination you will lie on your back. You will have small amount of gel spread over your skin on the areas to be examined. A handheld wand like instrument called a transducer will move over the area to be imaged. We may collect data from you using more than one ultrasound system.

Towards the end of the ultrasound examination, Dermatology will come into the room and confirm with the ultrasound sonographer where they will perform the biopsies and these sites will be marked. Specific ultrasound images will be obtained in these areas. The area of the skin to be biopsied will be cleaned. You then receive a medication (local anesthetic) to numb the biopsy site. This is usually given by injection with a thin needle. The numbing medication can cause a burning sensation in the skin for a few seconds. Afterward, you should not feel any pain or discomfort during the skin biopsies. For one biopsy, Dermatology will remove a small piece of skin from the affected ulcer area. The other biopsy will be done on non-sun exposed normal skin, such as the thigh.

A circular tool will be used to remove a small core of skin, including deeper layers. Stitches may be needed to close the wound. A bandage is then placed over the wound to protect it and prevent bleeding. Healing of the wound may take several weeks. Wounds on the legs tend to heal slower than those on other areas of the body.

Visit 3 (9 week)
As part of your standard of care you will have your wound care performed and a photo of your ulcer will be taken with a measuring grid. During this appointment you will undergo a research ultrasound examination.

Research Results
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?

Your doctor will discuss the risk of your wound care as this test is part of your standard clinical care.

Ultrasound imaging imposes no discomfort and does not involve radiation risks. Significant discomfort is not expected given that the ultrasound will be at the edge of the ulcer not over the raw central tender areas, but if you experience anxiety, stress, significant pain and/or discomfort during the ultrasound please notify the sonographer and the ultrasound can be stopped.

Biopsy Risk: As with any biopsy, bleeding is a possibility and bruising, pain, infection, allergic reaction to the numbing medicine used in the procedure, or damage to the structures beneath the skin site (such as an artery or a nerve). All biopsies cause a small scar. Additional risk from skin biopsies for patients with chronic non-healing diabetic and vascular ulcers includes infection, bleeding, ulceration, and/or further delay in wound healing. These risks are mitigated with biopsy from wound edge, and proper wound care instructions following biopsy.

Pregnant women will not be allowed to enroll on this study. Please tell your study doctor if you are pregnant or think you might be pregnant.

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?

Taking part in this research study is voluntary. You may decide to stop at any time. You should tell the researcher 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 researchers, or Mayo may stop you from taking part in this study at any time:

- If it is in your best clinical interest,
- If you do not 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?

There will be no direct benefit to you by taking part in this research study. It is for the benefit of research.

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:

- Two ultrasound examinations performed during your research study visits
- Two research skin biopsies
- Urine pregnancy tests (if applicable)

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?

We will pay you up to $350 for participating in the study. You will be paid $250 for completing the two research biopsies. You will be paid $50.00 for each ultrasound exam completed.

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. 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?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

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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. All electronic study data will be kept on password protected study staff computers and/or secured servers. All paper copies with patient information will be kept in locked file drawers in the study coordinator or principal investigators office.

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.
- 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
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 forever, unless you cancel it.

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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