A Study to Assess Metabolic Bone Disease of Prematurity Using an Acoustic Method

NCT04752098

November 5, 2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **November 5, 2024**
Not to be used after: **January 28, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Assessment of metabolic bone disease of prematurity using an acoustic method

IRB#: 19-001498

Principal Investigator: Azra Alizad, M.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 study is to test the effectiveness of a new ultrasound method in finding out about infant bone strength.
What's Involved	Study participation involves an ultrasound test on your leg. We will use a research ultrasound machine that meets FDA safety standards but is not FDA approved. We will also use a miniature microphone to record the inaudible sound of ultrasound. The actual ultrasound test lasts only a few seconds. We will repeat the ultrasound test in 3 different locations on one leg. The whole test, including the machine set up, will takes about 10-15 minutes. If you were born preterm (more than 3 weeks before their due date), the ultrasound test will be performed approximately once per month while you are in the hospital. If you were full term (born up to 3 weeks before their due date) the ultrasound test will take place once within the first 28 days of your life.

Key Information	The risks associated with this research study are not beyond the normal risk of clinical ultrasound and should not cause you any discomfort. Ultrasound at the intensity levels and duration used in this study has not been shown to present risk to human infants. There is no cost to you for any tests and procedures that are done only for this research study. The benefits, which may reasonably be expected, are potential benefits to babies in the future as a result of information gathered in the research study. This study is not designed to change the health care you receive.
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.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

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:** Azra Alizad, M.D. **Phone:** (507) 284-2511 **Co-Principal Investigator:** Jane Brumbaugh, M.D. **Phone:** (507) 284-2511 **Study Coordinator:** Fatima Zohra **Phone:** (507) 422-5069 **Institution Name and Address:** Mayo Clinic 200 1st 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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Why are you being asked to take part in this research study?

You are being asked to participate in this study because you are either a preterm baby or full-term baby.

Why is this research study being done?

This study is being done to test a new ultrasound method (obtained from your leg) to detect your bone strength.

Information you should know

Who is Funding the Study?
Mayo Clinic Ultrasound Research Center and the NIH are funding this study.

How long will you be in this research study?

This study will last for 1 visit if you are a full-term infant. The study will last up to 5 months if you are a pre-term infant.

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

Your bone strength will be evaluated by ultrasound. The ultrasound test if you were a preterm infant will be performed at up to 5 time points: within the first 28 days after birth, post 2 months, 3 months, and, if still hospitalized, at 4 months of age. In case of extended hospitalization, we may add another time point at 6 months. If you are no longer hospitalized at Visit 2 and 3, you will be seen as an outpatient.

If you are a full-term infant the test measurements will take place any time within the first 28 days after birth.

The results of this study will not affect the clinical decision and treatment for you.

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

The risks associated with this research study are not beyond the normal risk of conventional ultrasound and should not cause you any discomfort. Ultrasound at the intensity levels and duration used in this study have not been shown to present risk to human infants.

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.

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.

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?

You won't benefit from taking part in this research study. It is for the benefit of research. However, there may be potential benefits to children in the future as a result of information gathered in the research study. This study is not designed to change the health care you receive.

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 that are done only for the purpose of the research study. These tests and procedures are:

- Ultrasound research imaging system on your leg.

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.

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

You will receive $25 remuneration for each of the ultrasound visits.

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?

No biological samples will be collected as part of this research study. Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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 data from our experiment will be collected in digital form on our secure password protected server. All data will be stripped of your identity for subject privacy. We will set a code or identifier for you. Only, our study coordinator and principal radiologist have access to identifiable data.

The guidelines established by the Mayo Clinic Department of Health Sciences Research for the handling and storage of research data will be followed. The data will be made anonymous and your privacy protected in that manner. Additionally, data will be collected for research purposes only.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting

of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.

- 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.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition to the individuals listed above, 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
200 1st Street SW
Plummer Building PL 3-02
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

Signature of Parent(s)/Guardian for Child:

I give permission for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____
Printed Name of Child

_____
Printed Name of Parent or Guardian Date (mm/dd/yyyy) Time (hh:mm am/pm)

_____
Signature of Parent or Guardian

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