20-008408

Evaluation and Clinical Impact of Serum and Blood Metal Ion Levels in Patients with an Endoprosthesis

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MAYO CLINIC

Name and Clinic Number

Approval Date: **December 8, 2023**
Not to be used after: **December 7, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: "Evaluation and Clinical Impact of Serum and Blood Metal Ion Levels in Patients with an Endoprosthesis"

IRB#: 20-008408

Principal Investigator: Dr. Matthew Houdek 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	This study is being done to understand whether patients who previously had endoprosthesis (implant) surgery experience memory changes and heart problems after surgery. You have been asked to take part in this research because you have an endoprosthesis.
What's Involved	**Study Visit #1 (Baseline testing)** • Interview: The interview will be performed by the study coordinator who is a member of the research team. You will be asked to answer questions about your general health, surgeries, medications, and your memory and thinking skills. It will take about 20-30 minutes to complete.

	• Echocardiogram Studies • Blood draw of 50 mL (4-5 tablespoons) • Memory Interview: You will have an evaluation of your memory and thinking skills. You will answer questions and perform tasks that evaluate various thinking abilities such as concentration, memory, reasoning, and learning. This evaluation takes about 60 minutes. **<u>Study Visit #2 (1-year post enrollment) and Study Visit #3 (2 years post enrollment)</u>** • Echocardiogram Studies • Blood draw of 50 mL (4-5 tablespoons) • Memory Interview: You will have an evaluation of your memory and thinking skills. You will answer questions and perform tasks that evaluate various thinking abilities such as concentration, memory, reasoning, and learning. This evaluation takes about 60 minutes.
Key Information	When answering interview questions, you may choose not to answer any questions that you do not wish to answer. When completing tests for memory and thinking skills, you may experience some anxiety similar to taking a test in school. The risks of blood draw include pain, bruising, and rarely, infection at the site of the needle stick. Echocardiogram uses sound waves to look at your heart. The pressure on your chest during echocardiogram may be uncomfortable. We will use an image enhancement agent infusion during echocardiogram, and it carries a small but reversible risk of backache, headache or injection site reaction. You won't benefit from taking part in this research study. It is for the benefit of research.
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. 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(s):** Dr. Matthew Houdek **Phone:** (507) 284-8531 **Study Team Contact:** Sheri Merten **Phone:** (507)284-8531 **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

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.

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

You are being asked to take part in this research because you previously had an endoprosthesis.

Why is this research study being done?

The purpose of this research is to understand whether patients who previously had endoprosthesis surgery experience memory, thinking or heart problems. This study will help us determine if and how often these problems occur.

Information you should know

Who is Funding the Study?
The National Institutes of Health (NIH) is funding the study. The NIH will pay the Mayo Clinic to cover costs related to running the study.

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 be in the study for up to 2 years. This study involves three study visits at Mayo Clinic about 2 years apart. The initial visit consists of 2 separate tests and the subsequent visit in 2 years will consist of 2 follow up tests.

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

If you agree to be in the study, you will be asked to participate in the following:

Study Visit #1 (Baseline testing)	• Complete this Informed Consent Form • Interview: The interview will be performed by the study coordinator who is a member of the research team. You will be asked to answer questions about your general health, surgeries, medications, and your memory and thinking skills. It will take about 20-30 minutes to complete. • Echocardiogram Studies • Blood draw of 50 mL (4-5 tablespoons) • Memory Interview: You will have an evaluation of your memory and thinking skills. You will answer questions and perform tasks that evaluate various thinking abilities such as concentration, memory, reasoning, and learning. This evaluation takes about 60 minutes.
Study Visit #2 (1 year post enrollment)	• Echocardiogram Studies • Blood draw of 50 mL (4-5 tablespoons) • Memory Interview: You will have an evaluation of your memory and thinking skills. You will answer questions and perform tasks that evaluate various thinking abilities such as concentration, memory, reasoning, and learning. This evaluation takes about 60 minutes.
Study Visit #3 (2 years post enrollment)	• Echocardiogram Studies • Blood draw of 50 mL (4-5 tablespoons) • Memory Interview: You will have an evaluation of your memory and thinking skills. You will answer questions and perform tasks that evaluate various thinking abilities such as concentration, memory, reasoning, and learning. This evaluation takes about 60 minutes. If you are unable to come to Mayo Clinic for your follow up visit, study staff will offer to do the shorter visit by telephone.

I agree to participate in the optional echocardiogram of my heart.

☐ Yes ☐ No Please initial here: _____Date: _____

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?

- **Blood Draw:** The risks of drawing blood include pain, bruising, and rarely, infection at the site of the needle stick.
- **Memory and Thinking Tests:** Participants may experience some anxiety similar to taking a test in school when undergoing the tests of memory and thinking.
- **Echocardiogram:** The pressure on your chest may be uncomfortable. There is a small risk of a reaction to the image enhancement agent such as backache (1.2%), headache (2.3%), or injection site reaction (0.6%). If a reaction occurs, it typically occurs right away, and resolves within 30 minutes of stopping the infusion. Severe allergic and/or cardiopulmonary reactions are very rare (<1/10,000).

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.

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?

You won't benefit from taking part in this research study. It is for the benefit of research. Others who have had endoprosthesis surgery 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:

- Tests of memory and thinking
- Blood draws
- Echocardiograms

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 won't be paid for taking part in this study.

You will receive a per diem to cover additional costs as they relate to the study (i.e. lodging, meals and incidental expenses). This is a fixed rate determined by the federal government and subject to change yearly. The coordinator will discuss the current approved per diem rate at the time of consent.

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 data will be given a code rather than your name and stored in a secure database that only authorized users can access. 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.
In addition, all research materials will be stored in locked cabinets.

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.
- 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.

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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.

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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