Fully Automated High-Throughput Quantitative MRI of the Abdomen

6/25/26

NCT05294471

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Formal Study Title: Fully Automated High-Throughput Quantitative MRI of the Abdomen

Lead Researcher: Scott Reeder, MD, PhD
[redacted]

Institution: University of Wisconsin, School of Medicine and Public Health
Department of Radiology

Validation (3) IRON

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

The purpose of this research is to see if a new automated magnetic resonance imaging (MRI) method will be able to improve the images taken of the liver. This new method was designed to shorten the scan to about 5 minutes. This research will help determine if this shorter scan will still get all of the clinical information needed.

We invite you to take part in this research study because you are a patient with known/suspected iron overload syndrome that has agreed to participate in this research.

What will I need to do in this study?

The research team will ask you to complete one research visit lasting about one and a half hours to four hours. During this visit, information about you will be collected including race and ethnicity, your height and weight measured, and a 1 hour MRI scan will be done. Up to 20 subjects will be asked to repeat the MRI scanning procedures. The research visit for these subjects will take about 3 hours to complete.

We expect that you will be in this research study for one day.

IRB Approval Date: 6/25/2026
University of Wisconsin – Madison

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in the study if you are:

Comfortable having researchers ask questions about your health to makes sure it is safe for you to have an MRI scan.

Interested in contributing to scientific knowledge even though you won't benefit directly from the study.

You may NOT want to be in this study if you:

Want to be in a study that might help improve your own health.
Are nervous about being in a tight space or have claustrophobia.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints or think that participating in the research has hurt you, talk to the research team at [redacted]

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at [redacted] Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

If you agree to participate in this research, you will be asked to complete one research visit lasting about 1.5 hours to 3 hours. When you arrive at either the Wisconsin Institute for Medical Research (WIMR) or at the Department of Radiology in the UW Hospital, a research coordinator will meet you and will review the research procedures to be done, which will include the following:

- You will be asked a list of questions about your health to make sure it is safe for you to have a MRI scan.*
- Your height and weight will be measured and you will be asked some additional questions about your race/ethnicity.
- You will be positioned in the MRI scanner by the technologist that will be running the scan. A cushion will be placed underneath you. This cushion has some vials embedded in it that will be used to analyze the MR imaging obtained. You will be provided with ear protection and a “squeeze ball” that allows you to alert the technologist during the scan if you need anything You will be given other instructions on what’s required from you during the scan like intermittent 10-20 second breath holds. You will be in the scanner for about 60 minutes. Once the scan is complete, you will be done with your participation in this research.
- A total of 20 subjects will be asked to repeat these scanning procedures a second time. If you agree, this additional scanning will take another hour to complete for a total of about 3 hours. The research coordinator will let you know you are needed for this extra scan.

*If you have a history of metal in your eye(s) as a result of past injuries, hobbies, employment, or other life experiences, then an x-ray of your eye(s) may be required as a safety precaution. This x-ray is optional. However, if you have a history of metal in your

eye(s), and choose not to undergo the x-ray procedure, you may not participate in this research.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Results of tests or procedures done as part of the study

Things you tell the researchers about your health

We may need to review information currently in your medical records as well as information added to your medical records during the course of this study. This information could include information about your medical history, previous imaging (MRI, CT, x-rays, etc), and medications. We will get this information from your health care providers.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher:

Dr. Scott Reeder
[redacted]

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about abdominal imaging with MRI.

What are the study risks?

There is a risk that your information could become known to someone not involved in this study. There are also the following physical risks associated with participation in this research:

MRI: Although no known ill effects have been directly linked to exposure to the radio waves or the strong magnetic field used in MRI, it is not safe to scan people with certain types of metal in their bodies (pacemakers, body piercings, etc.). The person who schedules your MRI has been specifically trained to ask about possible metal in your body. It is important to answer the screening questions as accurately as possible. Sometimes patients experience a feeling of claustrophobia (fear of enclosed spaces) during the MRI scan. A microphone is built into the machine so that a technician will be able to hear you if you need help. There are no risks associated with the extra cushion positioned underneath you.

There are rare occasions when technical failures of the imaging equipment occur. These failures do not cause any risk to you and they won't make the scans feel any different while images are being taken. When technical failures happen, the images typically are not usable so we may want to repeat them. If a technical failure occurs during your research scan, we will contact you to let you know and to invite you to return for a repeat scan. Participating in these repeat scans is optional.

Orbital (eye) x-ray (optional): The risk of orbital x-ray is minimal. The average effective dose of radiation from this procedure is 0.1 millisieverts or mSv. For comparison, the average person in the United States receives a radiation exposure of 3.1 mSv per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is about the same amount you would normally receive in 12 days from these natural sources.

Pregnancy: Females who are pregnant should not participate. There are no known risks of MRI to an unborn child, but they may be possible. You should only take part in this study if you are certain you are not pregnant. If you are the parent/guardian of a minor who is considering being in this study, please note that we will ask all female subjects, in private, whether they are pregnant. We are required to follow Wisconsin law when determining whether we can tell you what your child answered.

For Minors: The study and MRI safety screen will be briefly discussed with you in private and will allow you to talk about any concerns with the study team. This will include the pregnancy screening question. Results of the pregnancy screening question will not be reported to your parents/guardians.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program, the Food and Drug Administration, and the Department of Health and Human Services,

Authorizing the research team to use your PHI means that we can release it to the people or groups listed above for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

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.

We will share information collected for this study with researchers or organizations outside UW-Madison, including GE Healthcare, the manufacturer of the MRI scanner, Resoundant Health, and Mayo Clinic. Resoundant Health and Mayo clinic will be helping with the analysis of some of the data collected for this research. No information that identifies you directly (name, MRN, DOB, etc.) will be shared with these organizations.

Will information from this study go in my medical record?

A medical record may be created for you if you do not already have one. Your medical record might say that you participated in this study, and a copy of this consent and authorization form might go in your medical record. Both you and your UW Health providers will be able to see this information.

Will I receive the results of research tests?

Part of the MRI we are using in this research study is the same quality as an MRI that you may have as part of your health care to assess liver iron. These images will be reviewed by a physician who normally reads such images (such as a radiologist). We will tell you

and your doctor the results of the liver iron assessment. The remainder of the MRI images will not be reviewed by a physician. As a result, you will not be informed of any unexpected findings. The results of your MRI will not be placed in your medical record.

What else do I need to know?

Will I receive anything for participating?
If you agree to take part in this research study, we will pay you $150 for your time and effort. If you participate in the repeat scan, we will pay you an additional $100.

Your information and images (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Permission to communicate about the study by email
We are requesting your email address so we can confirm visit details, if that is your preferred method of contact. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Dr. Scott Reeder at [redacted] You do not have to provide your email address to participate in this study.

How many people will be in this study?
We expect about 204 people will be in this research study at the UW Madison.

Who is funding this study?
This research is being funded by National Institutes of Health (NIH).

Financial Interest Disclosure:
Members of this research team have a personal interest in or might profit financially from the results of this study. This is called a “conflict of interest.” The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants or the quality of the data collected. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

What will happen to my data / images after my participation ends?
We will keep your data and images for an indefinite period of time, meaning we have no plans of ever destroying them. Keeping data and images for future research is called “banking.” The banked data and images will be anonymized after this research has been completed and will be kept in a secure location for use by researchers.

We will use the data and images in future research projects about MRI scanning of the abdomen. We may also use them for other types of research. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your treatment outside this study.

Are you interested in being contacted by staff about future research studies that you might be eligible for?

_____ YES

_____ NO

If yes, would you like to be informed by:

Phone _____

and/or

Mail/Email _____

The investigator will keep your contact information and diagnosis of iron overload on a password-protected computer. Only the investigator and designated research staff will have access to this information. The information will be kept for 7 years.

Agreeing to future contact does not commit you to participation in any research study. If you agree to future contact, you would be provided with information about the specific study and a consent form covering the details of the study if you want to learn more at that time.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant Date

Printed name of participant

Signature of person obtaining consent Date

Printed name of person obtaining consent

You are making a decision whether or not to have your child participate in this study. You do not have to sign this form. If you refuse to sign, however, your child cannot take part in this research study. If you sign the line below, it means that you have:

read this consent and authorization form describing the research study procedures, risks and benefits
had a chance to ask questions about the research study and your child's participation, and received answers to your questions
decided to allow your child to participate in this study
given authorization for the person's protected health information to be used and shared as described in this form

Printed name of child

Signature of subjects 15 - 17 years of age Date

Signature of parent or individual legally authorized to consent to the child's general medical care Date

Parent
Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of person obtaining consent and assent Date

Printed name of person obtaining consent