Control Research Informed Consent

Title of Study: *Iron Measurements and CCSVI in Multiple Sclerosis (MS)*

Principal Investigator (PI): E. Mark Haacke, PhD
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313-745-1395

Purpose

You are being asked to be in a research study of Magnetic Resonance Imaging (MRI) using a special technique called Susceptibility Weighted Imaging (SWI) for measuring iron in the brain. Because you are a normal healthy volunteer and have no injury or disease, you have been asked to take part in this study. This study is being conducted at Wayne State University. The estimated number of study participants (normal healthy volunteers) to be enrolled at Wayne State University is about 100 (50 MS patients and 50 healthy controls). **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, we will test a special technique called Susceptibility Weighted Imaging (SWI) and determine its ability to show the difference between blood vessels.

Study Procedures

If you agree to take part in this research study, you will be asked about your past medical/surgical history and 1.5 ml or ¼ teaspoon of blood will be taken for testing to assure you are safe to have a MRI scan and MRI contrast. For female subjects of childbearing age, a urine sample will be collected for pregnancy testing. Once you clear this screening, you will be asked to lie inside the MRI imager for not more than 90 minutes. The MRI imager is a long hollow tube that is open at both ends. The inside of the imager contains a large magnet and various radio antennas. The MRI has no moving parts and no x-ray radiation is involved. Instead radio-waves pass in and out of the body. These radio waves are exactly like those transmitted by radio stations. If you agree to participate, a coil (antenna) will be placed on your head, neck and under your neck to obtain signals from your body. While you are in the imager, you will be in contact with the operator by intercom, and he or she will be able to observe you at all times. You will be asked to have your heart beat or breathing monitored during the scan. You will also be given a government (FDA)-approved contrast agent that will highlight certain organs or tissues in your body (Gadopentetate dimeglumine - Magnevist). This contrast agent will be given through a small plastic tube (Intravenous Catheter or 'IV') placed in your vein prior to the MRI scan.

Data collection in this study is for research purposes only. The information from this scan will be given to your physician only if the radiologist identifies a structural problem. Your identity will remain confidential and your name will not be used in any publications. A random code number will be used to protect your identity.

Benefits

As a participant in this research study, there will be no direct benefit for you; however, information from this study may benefit people with multiple sclerosis in the future.

Risks

By taking part in this study, you may experience the following specific risks associated with MRI that have to do with the ability of the strong magnet that is part of the imager to attract iron –containing metal objects. You will be instructed to place everything you brought with you in a locker, including jewelry, cell phone, credit cards or anything else that could be damaged by the machine.

You will not be enrolled in this study if you:

- Have a cardiac pacemaker
- Have had surgery for an aneurysm
- Have had any major surgery within the past eight weeks
- Have metal fragments in or near the eye
- Have claustrophobia (fear of enclosed spaces)
- Have a serum creatinine > 1.8 mg/dL (blood test) to check your kidney function
- Are pregnant or nursing

Potential side effects related to the contrast agent (gadopentetate dimeglumine) are: Headache 4.8%, Nausea 2.7%, Coldness at the injection site is 2.3%, Dizziness of 1% and serious allergic reaction of less than 1% which may include itching, rash, hives, facial swelling and difficulty in breathing rarely resulting in death.

The MRI contrast agent is passed through breast milk and also goes through the placenta during pregnancy. Risks to fetus or newborns has not been studied. Therefore, if there is any possibility that you are pregnant or you are nursing, you should not participate in this study.

In addition to the potential side effects listed above, the following side effects have happened in less than 1% of subjects receiving the contrast:

Chest pain or tightness, a warm, or burning sensation; back pain, fever, weakness, coldness, swelling at or near the injection site, tiredness, shaking, shivering, stiffness in arms or legs, swelling in other places in your body, hip pain. High or low blood pressure, changes in heart rate, severe headache, paleness, blood clots and heart attack. Stomach pain, teeth pain, drooling, dry mouth, vomiting, constipation or diarrhea. Feeling anxious, thirsty, not wanting or unable to eat, eye pain, changes in vision or tearing, tingling in arms or legs or seizure. Sore throat, runny nose, sneezing, coughing, wheezing. Heavy sweating, severe skin problems, ringing in the ears, ear pain.

Acute renal failure: subjects with reduced ability of the kidneys to function have seen worsening kidney impairment, mostly with in 48 hours of contrast injection.

You will not be scanned if you have severe kidney problems.

A very rare body wide condition (Nephrogenic Systemic Fibrosis – NSF) may be caused by MRI contrast agents and has been seen in people with severe or end stage kidney problems. This condition causes thickening and hardening of the skin and may also affect other organs in your body that may result in minor to life threatening problems.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives

You may choose not to participate in this study.

Study Costs

Taking part in this study will be of no cost to you or your insurance company. There will be no screening cost to determine your eligibility.

Compensation

For taking part in this research study, you will be paid for your time and inconvenience. On the day of your MRI you will receive $50 dollars (in cash).

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University or The Detroit Medical Center and any other facility involved with this study. If you think that you have suffered a research related injury, contact the PI right away at (313)-745-1395.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

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Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. If you have any side effects that are very serious or if you become ill during the course of the research study you may have to drop out, even if you would like to continue. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate.

Questions

If you have any questions about this study now or in the future, you may contact E. Mark Haacke, Ph.D. or one of his research team members at the following phone number (313)-745-1395. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

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Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant	Date
Printed name of participant	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

APPROVAL PERIOD
MAY 27 '10 MAY 26 '11
HUMAN INVESTIGATION COMMITTEE

Signature of translator	Date
Printed name of translator	Time

Continue to HIPAA Authorization on next page

Participant's Initials

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HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. This review occurs at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, address (street address, city, state and zip code), elements of dates, telephone numbers, e-mail address, medical record number, and any unique identifying numbers or characteristics or code.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: There will be no disclosures.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project.
- WSU's HIC and the Institutional Review Boards (IRB).
- Authorized members of WSU's workforce and DMC's workforce who may need to access your information in the performance of their duties to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.
- The study Sponsor or representative, including companies it hires to provide study related services, which include: Departmental (WSU), NIH.
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____

Signature of participant Date

_____

Printed name of participant

APPROVED

MAY 2 7 2010

WAYNE STATE UNIVERSITY
HUMAN INVESTIGATION COMMITTEE