Rapid MRI for Acute Pediatric Head Trauma
NCT03291964
7/19/2017

CO1450

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#:17254

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

Clinical Research Consent Summary

TITLE: *QuickBrain MRI for Pediatric Head Trauma: A Pilot Study*

PRINCIPAL INVESTIGATOR: David Sheridan MD, MCR (503) 494-1691

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

1. The purpose of this study is to learn more about MRI and its accuracy for pediatric head injuries. Magnetic resonance imaging (MRI) does not require radiation.
2. In this study, we will learn about MRI for this specific indication. We want to learn
    a. If it is possible to obtain it in the Emergency Room (ER),
    b. how well it can identify injuries in the brain,
    c. and how long it takes. We currently use it routinely for other conditions and prior research shows it should work well for head injuries.
3. The research study is being funded by the Friends of Doernbecher Foundation.
4. If you join the study, your child will undergo an MRI during this stay and no further follow up or questions are needed.

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#:17254

Clinical Research Consent and Authorization Form

TITLE: *QuickBrain MRI for Pediatric Head Trauma: A Pilot Study*

PRINCIPAL INVESTIGATOR: David Sheridan MD, MCR (503) 494-1691

CO-INVESTIGATORS:
Nathan Selden MD (503) 494-9000
Susan Rowell MD (503) 494-9000
Mubeen Jafri MD (503) 494-9000
David Pettersson MD (503) 494-9000
Craig Newgard MD (503) 494-9000
Matthew Hansen MD (503) 494-9000

FUNDED BY: Friends of Doernbecher Foundation

PURPOSE:
Your child has been invited to be in this research study because she/he is being evaluated for a head injury with neuroimaging. The purpose of this study is to learn more about a rapid form of MRI for detection of head injuries rather than the standard CT imaging.

The MRI we are studying is experimental. We do not know if it is better than the usual approach for diagnosing head injuries.

CT imaging involves exposure to radiation during the scan, while an MRI does not require radiation. If MRI is shown to be better than the usual approach, the study may eliminate radiation exposure during imaging for head injuries.

Study participation involves a one-time MRI during your child's acute evaluation and should take less than 3 minutes to complete. There is no follow-up needed.

A total of 100 subjects will be enrolled in this study over a one year period. All subjects will undergo the same imaging study.

PROCEDURES:
Your child is being asked to participate in this study because she/he is already being evaluated for a head injury with diagnostic imaging in the emergency department.

CO1450

If you agree to your child's participation, all of the standards of care will remain the same, but your child will undergo one additional imaging test. This test will not change her/his care after it is completed and the same teams will care for her/him throughout her/his stay. The current standard of care is to undergo a head CT.

Your child will undergo the same evaluation and care by her/his medical team. However, she/he will be taken to the MRI suite to undergo a 2-3 minute imaging test of her/his brain after completion of the head CT. The additional time to participate in the study is less than 15 minutes; this includes the 3 minute imaging study and time to travel to the MRI suite which is within the same building as the emergency department but down an elevator. There is no follow up needed or further tests your child will undergo for study purposes.

Your child's medical chart will be reviewed by the study team for information related to the care she/he received during this stay. This includes: her/his final diagnosis, length of hospital stay, any procedures, mechanism of injury and basic demographics including age, gender and time of hospital visit.

ACCESS TO YOUR TEST RESULTS

You will not have access to your child's MRI results, neither will your medical team. However, your child is undergoing the current standard imaging that will help guide her/his care.

The MRI scan is being done to answer research questions, not to examine your child's brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan may not show problems that may be picked up by a clinical MRI scan. If we find an abnormality that requires urgent follow-up, we will contact you and your child's doctor (with your permission) to help answer questions and get the right follow-up care for your child. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

RISKS AND DISCOMFORTS:

The magnetic resonance imaging (MRI) machine is a powerful magnet. There are no known risks from the magnet itself. However, if your child has a metal in her/his body, the magnet may cause the metal to move. If you know of any metal in your child's body, tell the research team because your child may not be able to have an MRI. Review any dental treatments your child has had with the research team, since these may involve metal. The most common discomfort of an MRI is the length of time your child must lie still or flat while the scan is being performed. Some people with claustrophobia (fear of closed spaces) may find the MRI machine too confining. Finally, the MRI scanner makes loud beeping or thumping noises, so your child may be offered protective earplugs to wear during the scan. As with the head CT that is obtained for clinical care, some children experience anxiety and may need medications for this. However, they will not receive any medications that fully put them to sleep or make them unresponsive.

BENEFITS:

Your child may or may not personally benefit from being in this study. However, by serving as a subject, she/he may help us learn how to benefit patients in the future.

ALTERNATIVES:

You may choose not to have you child in this study. She/he will receive the same care she/he would have whether in the study or not.

CONFIDENTIALITY

We will take steps to keep your child's personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about your child as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to have your child be in this study, you are giving permission (also called authorization) for us to use and disclose your child's health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about your child in order to conduct and oversee this research study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, Friends of Doernbecher Foundation and the funder's representatives
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your child's records, including her/his medical records.

We will not release information about your child to others not listed above, unless required or permitted by law. We will not use your child's name or her/his identity for publication or publicity purposes, unless we have your special permission.

OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments.

When we send information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your child's information could be used and re-released without your permission.

We may continue to use and disclose your information as described above indefinitely.

COMMERCIAL DEVELOPMENT:
Information about your child or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you and your child if this happens. You and your child will not have any property rights or ownership or financial interest in or arising from products or data that may result from your child's participation in this study. Further, you will have no responsibility or liability for any use that may be made of your child's information.

COSTS:
Some of the services or items in this study are part of the regular treatment for your child's condition. These would be performed or used even if your child was not in this study. The costs for these services or items will be billed to your child's insurance. You will be responsible for any costs your child's insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If your child is uninsured, you will be responsible for these costs.

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your child's regular treatment.

LIABILITY:
If you believe your child has been injured or harmed as a result of participating in this research and require treatment, contact **David Sheridan MD MCR at 503-494-9000.**

If your child is injured or harmed by the study procedures, she/he will be treated. OHSU and the Friends of Doernbecher Foundation do not offer any financial compensation or payment for the cost of treatment if your child is injured or harmed as a result of participating in this research. Therefore, any medical treatment your child need may be billed to you or your insurance.

However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact **David Sheridan MD MCR at 503-494-9000**

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your child's participation in this study is voluntary. Your child does not have to join this or any research study. You do not have to allow the use and disclosure of your child's health information in the study, but if you do not, your child cannot be in the study.

If your child does join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your child's health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your child's health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

David Sheridan MD MCR
sheridda@ohsu.edu
3181 SW Sam Jackson Park Rd
Portland, OR 97239

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

There are no additional visits or procedures needed if you choose to withdraw from the study.

If in the future you decide you no longer want your child to participate in this research, we will remove her/his name and any other identifiers from her/his information, but the material will not be destroyed and we will continue to use it for research.

You may be removed from the study if the investigator or funder stops the study, your child becomes pregnant, she/he develops serious side effects, and her/his disease gets worse prior to obtaining the imaging.

We will give you any new information during the course of this research study that might change the way you feel about your child being in the study.

Your child's health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your child's clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your child's care from another doctor who is in no way involved in this project. Your child does not have to be in any research study offered by her/his physician.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Printed Name	Signature	Relation to Subject	Date
Printed Name	Signature	Relation to Subject	Date

Subject Printed Name		
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the subject in _____

(state language) by an individual proficient in English and _____ (state language).

If applicable:

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.