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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 08.2013)

Project Title:Assessment of novel MRI quantification free breathing technique in evaluation of liver lesions

Principal Investigator: Vikas Gulani, MD, PhD

Introduction/Purpose

You are being asked to participate in this research study because you are scheduled to undergo a liver intervention or MRI exam of your liver. The purpose of the research study is to test new methods that could improve MR (Magnetic Resonance) imaging for liver lesions. The goal of this technique is to rapidly scan the patient and to predict with greater certainty what type of lesion a patient has. We will compare the imaging data gathered from this new technique with your other imaging tests and biopsy results to evaluate the accuracy of this new technique.

MRI abdominal imaging and liver MRI are very common abdominal exams. MRI is extremely important in liver evaluation because it can give high quality images without exposure to radiation. In reality, liver MRI exams can be challenging for patients as well as for the technologists, due to the need to hold your breath during the exam. Breath holding is needed in MRI exams to avoid blurry and poor quality images. However, holding your breath can be tiring for sick people. We have developed new fast MRI techniques which can acquire high quality images even during free breathing activity by the patient. These techniques also provide additional information about the liver that could help evaluate liver problems without the need for biopsies. If successful, these techniques will provide accurate, fast and convenient liver evaluation. Such imaging tests will improve accuracy of diagnosis, improve patient comfort, potentially avoid more invasive means of diagnosis such as biopsy, and result in overall cost savings.

You will be one of 170 patients that will be enrolled for this study.

Study Procedures

As a participant in this study, you will be asked to come to the University Hospitals Radiology Department. Your participation in this study will involve a single visit to the MRI section.

If you are scheduled for a liver intervention and you agree to participate in the study, you will undergo a contrast enhanced research MRI examination of your liver prior to your intervention procedure. The research MRI will be conducted before the liver Intervention.

If you are scheduled for a clinical MRI of the liver and you agree to participate in this study, you will undergo an additional contrast enhanced research MRI examination of your liver on a work day that is suitable for you. This research MRI scan will be on a separate day from, and in addition to, any clinical MRI scan you may undergo or have undergone in the past.

The entire procedure will take about 1 hour and the actual scanner time will be approximately 45 minutes. The study will also involve administration of intravenous gadolinium-based contrast agent that is similar to current standard of care.

Risks

Risks to patients in this study include all those risks currently associated with MRI. These include discomfort involved with being required to lie still in a small space. If this occurs, we will stop the scan and take you out of the magnet. These risks are all considered rare (likely occurring in fewer than 10 of every 100 patients). Patients with severe renal dysfunction are at risk of nephrogenic systemic fibrosis (NSF), a rare and serious syndrome that involves fibrosis, or scarring of the skin, joints, eyes, and internal organs. Due to this risk, patients with severe renal

dysfunction will be excluded from the study. In addition, very small amounts of MRI contrast agents deposit in certain tissues of the body including regions of the brain, in patients who have received multiple doses of these agents. No known harm has been associated with the deposition, before or since the description of this deposition in 2014. More than 300 million doses of gadolinium contrast have been given in humans since their first use.

Certain metals are not safe to go into an MRI scanner. You will be asked to remove all jewelry and change out of clothing containing metal prior to the study. You will also fill out an MRI safety questionnaire that allows us to screen you for metals that cannot go into the scanner. There is a very slight risk of an allergic reaction with the contrast material. Such reactions usually are mild and easily controlled by medication. If you experience allergic symptoms, a radiologist or other physician will be available for immediate assistance.

Participation in this study may involve risks that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.

Reproductive Health/Sexual Activity

Being a part of this study while pregnant may expose the unborn child to significant risks. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, you will be asked whether you are pregnant. If it is possible that you may be pregnant, a pregnancy test will be done, and it must be negative before you can enter this study.

Benefits

There are no direct health benefits for your participation in this study. However, the results of this study may help provide more accurate and faster MRI evaluation in future patients with liver lesions.

Alternatives to Study Participation

You may choose not to participate in this study and it will not affect your routine clinical care in any manner.

Student/ Employee Rights: Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Financial Information

The study will pay for the contrast enhanced MRI scans. However you or your insurance company will be responsible for payment of your routine clinical care.

You will be paid $100 for your participation in this study.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury.

Confidentiality

The information about you collected for the study will be stored both on paper and computer records, without identifying you by name. Your personal information will be separated from the study information, which will be labeled with a code. The study doctor will keep a list that links the code number to your

name. This list will be stored in a locked file cabinet only accessible to the study doctor and research staff.

You will not be identified by name in any report or publication. Your records may be disclosed if required by law.

Termination of Participation

The study doctor without your consent may discontinue your participation in this study if the study doctor determines it is not in your best interest to continue.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Assessment of novel MRI quantification free breathing technique in evaluation of liver lesions" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Vikas Gulani, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who is working on this research project will know that you are in a research study and will see and use your PHI. The researchers working

on this study will collect the following PHI about you: your age, gender, medical record number, clinical examination, laboratory workup, information about your liver disease, current and any previous liver imaging data, comorbidities, medications, MRI technical parameters (TR, TE, Matrix size, Coil used, flip angle, temporal resolution, slice thickness, FOV, number of slices, parallel imaging acceleration factor, total image acquisition time, total number of images), arterial and venous signal enhancement data, measured perfusion and diffusion parameters.

This PHI will be used to validate a new method that could lead to faster and more accurate assessment of liver lesions. Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: the investigator; co-investigators; members of the research staff; other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Vikas Gulani at 11100 Euclid Avenue, Cleveland, Ohio 44106; If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services

Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may

review your study records. If the Food and Drug Administration (FDA) regulates this study, there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Vikas Gulani, MD, PhD can also be contacted at (216) 844-3112. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about concerns regarding the study, research participant's rights, research- related injury, or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

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x	
Signature of Participant	Date
x	
Printed name of the participant	Date

**not required unless participant is illiterate*

x	
Signature of Witness	Date
x	
Printed name of Witness	Date

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	
Printed name of person obtaining informed consent	