# Evaluation of the efficacy of contrast enhanced ultrasound compared to MRI for differentiation of hepatic lesions

**NCT03652636**

**Informed Consent Document**

**08/20/2019**

**INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH**

**Evaluation of the efficacy of contrast enhanced ultrasound compared to MRI for differentiation of hepatic lesions**

**About this research**

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**Taking part in this study is voluntary**

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with the Indiana University School of Medicine, Department of Radiology and Imaging Sciences.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to find out if the use of a type of intravenous contrast containing tiny bubbles (Lumason, Bracco Diagnostics Inc) during ultrasound imaging allows us to distinguish two kinds of liver lesions (focal nodular hyperplasia and hepatic adenoma) as well as does the usual imaging method, contrast-enhanced magnetic resonance imaging (MRI).

You were selected as a possible participant because your physician has referred you for an MRI scan to image your liver lesion(s).

The study is being conducted by Jordan K. Swensson, M.D., of the Indiana University School of Medicine, Department of Radiology and Imaging Sciences.

**HOW MANY PEOPLE WILL TAKE PART?**

If you agree to participate, you will be one of 40 participants taking part in this research.

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

You have had or will have a MRI scan with contrast performed of your liver as ordered by your physician. This is the standard imaging scan for a patient with your condition. A physician either has explained or will explain to you what occurs during a MRI scan of the liver, and the risks of the procedure. You may sign a separate consent form for the physician to perform the MRI scan. Information from your medical record will be collected and used for this study as related to the standard of care MRI.

After the MRI, you will be scheduled for an ultrasound scan with Lumason performed on your liver, at University or Methodist Hospital. This is the imaging scan that we are studying in this research. You will be given instructions on how to reach this facility.

At the ultrasound suite, a person trained in inserting a needle into a vein will clean an area on the inside of one of your elbows. This person will then inject less than one ounce of a saline solution containing Lumason into a vein in this area. A technologist will then spread a gel that helps us see the liver better over the skin above your liver. The radiologist will move a "wand" over the liver to get ultrasound pictures. If the pictures are unclear, a second injection of the same amount of Lumason may be performed, and more pictures will be taken. The entire ultrasound scan should take 30-45 minutes to perform. You will then be free to leave and your participation in the study will be complete.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

There is a small risk of pain, swelling, and/or infection at the site where Lumason is injected. To reduce this risk, only personnel trained in performing this procedure will do so.

Lumason has rarely been associated with heart, circulatory, and breathing problems just after it is injected. It can also rarely cause an allergic reaction (rash, difficulty breathing).

There is theoretical risk that the gas bubbles in the contrast may lead to temporary blockage of tiny arteries found throughout the body, which could lead to serious damage to internal organs and tissues. However, there have not been any reported cases of this happening, and the drug has been FDA approved for use in evaluating liver lesions.

To reduce these risks, you will be monitored during and for several minutes after the injection. Trained personnel and medications to treat these problems are quickly available should they occur. A group of patients at highest risk (history of cardiac shunting) will not be allowed to participate.

In any research study, there is the risk of loss of confidentiality. We will reduce this risk by limiting the number of people who can see study data that is directly linked to you. If study data is released to others, all information that could be used to identify you as a study participant will be removed.

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

We don't expect you to receive any benefit from taking part in this study, but we hope to learn things which will help scientists in the future.

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study, and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) etc., who may need to access your medical and/or research records.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

**WILL I BE PAID FOR PARTICIPATION?**

You will not be paid for participating in this study.

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: cost of contrast-enhanced MRI scan of the liver, and cost of the radiologist who reads the scan. This is a standard of care procedure that will be the responsibility of you or your insurance.

You will not be responsible for these study-specific costs: contrast-enhanced ultrasound of the liver, cost of the Lumason contrast, reading of the scan by the radiologist.

**WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?**

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study, contact the researcher, Jordan K. Swensson, M.D., at (317) 944-1837. After business hours, please call (317) 944-5000 and ask for the radiology resident on-call.

In the event of an emergency, you may contact Dr. Swensson at (317) 367-9075.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, contact the principal investigator, Dr. Swensson, at the phone number listed above.

**PARTICIPANT'S CONSENT**

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

**Participant's Printed Name:**_____

**Participant's Signature**:_____ **Date**:_____

**Printed Name of Person Obtaining Consent:**_____

**Signature of Person Obtaining Consent**:_____ **Date**:_____