Contrast-enhanced Ultrasound for Complex Kidney Lesion Diagnosis (CEUS CKD)

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: May 25, 2016
IRB Study # 15-1866
Title of Study: Contrast-enhanced Ultrasound for Complex Kidney Lesion Diagnosis (CEUS CKD)
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What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to evaluate contrast-enhanced ultrasound for kidney malignancies. You are being asked to be in the study because you have a kidney disease and have had a lesion identified in previous clinical imaging.

Are there any reasons you should not be in this study?
You should not be in this study if less than 18 years of age, unable to give consent, an institutionalized subject (prisoner or nursing home patient), pregnant or breastfeeding. You should also not participate in this study if you have any contraindication for ultrasound contrast

imaging.

How many people will take part in this study?
There will be approximately 75 people in this research study.

How long will your part in this study last?
Your participation in this study will be limited to 1 study visit. However, we will be contacting your primary provider for follow-up ultrasound and blood tests after your study visit.

What will happen if you take part in the study?
If you decide to participate, you will be escorted by the research coordinator to a dressing room, where you will change into a gown. Then, you will be asked to lie on an examination table and positioned. Once you are positioned, gel will be applied to the your back or side and an ultrasound will be done. Imaging will be performed by a trained medical personnel.

At the time of imaging, FDA-approved lipid-shell microbubble contrast agent (Definity®) will be administered intravenously by a nurse or trained medical personnel. The total imaging time is anticipated to be less than 15 minutes.

If you have a second lesion requiring an additional dose of contrast agent, and you agree to receive the second dose, it will be administered 30 minutes after the start of the first dose.

Optional Consent to Receive Second Dose (only in cases when a second lesion is present):
If you have a second lesion you may receive an additional second dose of contrast agent which would be administered 30 minutes after the start of the first dose. Please indicate whether you agree to receive a second dose by putting your initials next to one of the following choices:
_____ (initials) No, I do not agree to receive a second dose of the contrast agent.

_____ (initials) Yes, I agree to receive a second dose of the contrast agent.

You will be monitored by medical professionals for 30 minutes after the last contrast dose is administered. Once images are collected, they will be deidentified for interpretation and analysis.

A urine sample will be collected prior to and after imaging. After study imaging, you will continue with your normal clinical care as ordered by your physician. The images that we collect are for study purposes, and will not be used to guide your future care. If you undergo a biopsy or surgery, we will review your pathology report in order to compare the results of your biopsy with the images that we collect. Your chart will be reviewed for a minimum of 1 year after the initial imaging study for blood and urine tests as well as repeat imaging studies.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

You will be given a contrast agent (Definity) for the research images. Definity (perflutren lipid) is an FDA-approved lipid-shell microbubble contrast agent that may be administered by an intravenous (IV) bolus or infusion. Currently, this contrast agent is approved for use in patients with echocardiograms that are difficult for physicians to see the specific features of the heart so that they can see them better. Since we will use the contrast agent for ultrasound imaging in the kidney and not the heart, we will be using Definity in a way that was not specifically approved by the FDA, but we do not think that this way of using Definity will put you at any additional risks.

The most common side effects of Definity that have been reported are (% of patients experiencing): headache (2.3%), back and renal pain (1.2%), flushing (1.1%) and nausea (1.0%). There were no differences in the overall incidence based on age, gender, or route of administration.

The real risk of Definity in our study is to the small number of potential patients with undiagnosed allergy to Definity. Post-marketing reports have included allergic reactions and other serious but non-fatal adverse reactions, typically within 30 minutes of drug administration. In order to avoid a potentially fatal event, EpiPen® (epinephrine) injections will be kept near the ultrasound machine for all patients.

In order to administer the contrast an intravenous catheter (IV) will be inserted into a vein in your arm. You may experience pain or bruising at the site on your arm where the IV was inserted. Localized clotting, irritation, lightheadedness fainting or infection may rarely occur.

What are the risks to a pregnancy or to a nursing child?

If you are pregnant or are planning to get pregnant, you will not be allowed to participate in this study. If you are of childbearing age, you will be required to undergo a pregnancy test at no charge to you. You will not need a pregnancy test if you are surgically sterile or post-menopausal (no menstrual cycle for one year). If later you learn that you were pregnant during the study, you are asked to contact the study doctor immediately for further instructions. By signing this consent form, you confirm to the best of your knowledge that you are not pregnant now.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

All of your research records will be stored using your initials and a case number only. The research records will be kept in a locked cabinet within a locked office suite at UNC. The master file linking your name to your case number will be maintained on a password locked computer at UNC and will only be accessible by the study coordinator.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will be receiving $50 for the initial imaging study and parking voucher. Upon complete collection of follow-up studies (routine ultrasound, blood and urine tests at 1 year after imaging study), you will receive an additional $50. If you are not a UNC patient and require travel to UNC to obtain the 1-year US, you will receive $75 instead of $50.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form. A description of this clinical trial will be available on www.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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent