Principal Investigator: Leigh Casadaban, MD
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Study Title: Genicular artery embolization for knee osteoarthritis: Evaluation of the correlation between subjective scoring system response and objective markers of inflammation

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?
This study plans to learn more about changes in the fluid in your knee joint (synovial fluid), imaging findings and physical function performance-based tests before and after Genicular Artery Embolization (GAE) (a procedure to help decrease knee pain). You are being asked to be in this research study because you have knee pain and would like to undergo GAE. Results of this study may help investigators better understand how this procedure works and who will benefit the most or least.

Other people in this study
Up to 46 people from your area will participate in the study.
Up to 46 people around the country will be in the study.

What happens if I join this study?
If you join the study, you will be asked to undergo a knee fluid aspiration (arthrocentesis), a contrast-enhanced MRI and physical function performance-based tests before and after the GAE procedure. If you cannot participate in some of the study tests, you may still be included in the study for the remainder of tests. Your participation will last for 12 months after the procedure. You will follow-up in clinic at 1 month and 3 months after the procedure. You will have a telephone call to complete questionnaires at 6 months and 12 months after the procedure.

Knee fluid aspiration (arthrocentesis): Using local anesthesia, the area around your knee will be numbed. Then, with ultrasound guidance, a thin needle will be inserted into the upper part of the knee joint. Up to 10mL of synovial fluid will be collected for analysis.

Contrast-enhanced MRI: Contrast enhanced MRI sequences will be added to the pre-treatment and 3-month post-treatment standard MRI exam. These will be analyzed to determine the severity of your synovial inflammation.

Physical function performance-based measures: A 30-second chair stand test will be completed. You will be asked to sit in a chair, place your hands on the opposite shoulder crossed at the wrists. Keeping your feet flat on the floor, back straight, and arms against your chest, you will rise to a full standing position, then sit back down again and repeat this for 30 seconds.

A guided 50-foot timed walk will also be completed. You may use an assistive device, but it should remain consistent for all tests.

Questionnaires: Visual Analogue Scale (VAS) and Knee Injury and Osteoarthritis Outcome Score (KOOS)

The following table summarizes each visit for the duration of this research study.

Procedures	Visit -1: Screening	Visit 1: Treatment	Visit 2: Month 1	Visit 3: Month 3	Visit 4: Month 6	Visit 5: Month 12
Medical history	X					
Physical exam with vital signs	X		X	X		
Questionnaires	X		X	X	X	X
Performance based measures	X		X	X		
Knee MRI	X			X		
Pregnancy test		X				
Intravenous blood draw		X				
Synovial fluid aspiration with WBC		X		X		
GAE		X				

What are the possible discomforts or risks?
Discomforts you may experience related to the study interventions while in this study are as follows:

Knee arthrocentesis: pain, infection, bleeding, and injury to the knee area (<1%).

Contrast-enhanced MRI: allergic reaction, nausea, vomiting (<2%).

In this study we will take Magnetic Resonance Images (MRI's). The MRI machine uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal to heat up and electronics to stop working.

You should NOT have an MRI if you have metal or electronic devices inside your body. Heart pacemakers and insulin pumps are examples of electronic devices.

The MRI machine is a small round tube. It might make you uncomfortable if you do not like tight spaces.

The most common side effect of having an MRI is flashing lights in the eyes. This is caused by the magnetic waves and is not harmful. Some people also experience warmth and reddening of the skin. This usually goes away after a few minutes.

If you are pregnant, be sure to tell the person giving you the MRI.

Physical Function tests: pain or injury (<1%).

There are additional risks related to usual care, which you should discuss with your doctor.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

If you become pregnant, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus, which are currently unclear.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?
This study is designed for the researcher to learn more about changes that occur to the knee after GAE.
This study is not designed to treat any illness or to improve your health.

Who is paying for this study?
The Society of Interventional Radiology (SIR) Foundation is funding the study. The study will only pay for procedures not considered standard of care, as detailed below:

- Knee fluid aspiration (arthrocentesis)
- Contrast portions of the knee MRI
- Physical function performance-based tests

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

You and your insurance will have to pay for the visits, procedures and care that are routine care for your medical condition. You will be responsible for co-payments and deductibles that are standard for your insurance coverage.
Questions about costs that will or will not be covered by your insurance should be addressed to the customer care team for UCHealth Billing, 1.866.429.6045, OR CU Medicine Group Billing, 303.493.7700, who are available Monday-Friday, 8 a.m. to 5 p.m.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should call Leigh Casadaban, MD immediately. Call the Hospital operator 720-848-0000 and ask for Leigh Casadaban, MD to be paged.

In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

Who do I call if I have questions?
The researcher carrying out this study is Leigh Casadaban, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Leigh Casadaban, MD at 720-848-0000. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Leigh Casadaban, MD with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055 or email comirb@ucdenver.edu.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will see my research information?
The University of Colorado Denver | Anschutz Medical Campus and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside UCHealth and its affiliates may not be covered by this promise and your information may be disclosed without your permission.

We will do everything we can to keep your records confidential. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Leigh Casadaban, MD
University of Colorado Anschutz Medical Campus
12401 E 17th Avenue, Aurora CO 80045

Both the records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Office of Human Research Protection and the Food and Drug Administration (FDA) that protect research participants like you
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The Society of Interventional Radiology (SIR) Foundation, who is the company paying for this research study.
- Relevant operational, regulatory and compliance offices at University of Colorado Denver | Anschutz Medical Campus involved in the oversight of the study
- The study doctor and his/her team of researchers.

Your information may be used and disclosed, to do the research, to study the results, and to make sure that the research was done right.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research participants, like you, private.

You have the right to request access to your personal health information from the investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, email, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Tissue samples and the data with the samples.

What happens to Data, Tissue, Blood, and Specimens that are collected in this study?

Investigators involved in this study work to find the causes and cures of disease. The data, tissue, blood, and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, or the tissue, blood, or other specimens are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, the facilities involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Witness:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____