COMIRB
APPROVED
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Principal Investigator: James Genuario, MD
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Study Title: Effect of warmed irrigation fluid on immediate post-operative pain scores in patients undergoing hip arthroscopy**.**

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 the effect of warm arthroscopic fluids in decreasing immediate post-surgical pain.

You are being asked to be in this research study because you have been indicated to undergo hip arthroscopic surgery for femoral acetabular impingement syndrome.

Other people in this study
Up to *60* people from your area will participate in the study.

What happens if I join this study?
If you join the study, you will undergo standard care for your hip surgery. Nothing about the surgical procedure or peri-operative care will change by participating in the study. The only change that will be made if you decide to participate is you may be randomized to receive pre-warmed arthroscopic fluids during your surgery as compared to room temperature fluids. The duration of the study is from the day of your pre-operative appointment until your two-week post-operative visit. There are risks associated with arthroscopic hip surgery that are separate from the risks associated with being in the study. The risks of surgery will be discussed with you separate from this form.

How We Decide Which Study Group You Will Be In?
This study will have different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care.

What are the possible discomforts or risks?
Discomforts you may experience while in this study include routine pain from undergoing hip surgery. We do not anticipate any additional risk or discomfort based upon your involvement in this study. We will not change how we manage your surgical pain based upon your participation in this study.

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.

What are the possible benefits of the study?
This study is designed for the researcher to learn more about the role of warmed arthroscopic fluids in immediate post-operative pain. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

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?
It will not cost you anything to be in the study.

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.

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.

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 Dr. James Genuario or the on call physician immediately. The clinic phone number is 303-694-3333.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you 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 Dr. James Genuario. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Genuario at 303-694-3333. 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 Dr. Genuario with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?
The University of Colorado Denver (UCD) and its affiliated hospital(s) 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
- Steadman Hawkins Clinic Denver

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 the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality 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 (PI), 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.

Dr. James Genuario
Steadman Hawkins Clinic Denver
175 Inverness Drive W
Suite 200
Englewood, CO 80112

Both the research 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, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

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 subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

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

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Your social security number
- 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

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (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:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Signature:_____ Date_____

Witness Print Name:_____

Witness of Signature ☐ Witness of consent process ☐