The University of New Mexico Health Sciences Center
Consent to Participate in Research

Evaluating the efficacy of micro-fragmented adipose tissue and intra-articular corticosteroid injections for symptomatic knee osteoarthritis: a randomized, placebo controlled study

11/07/2019

Purpose and General Information

You are being asked to participate in a research study that is being done by Dustin Richter, MD, who is the Principal Investigator, and his associates. This research is being done to evaluate the efficacy of corticosteroids and Lipogems® injections for knee osteoarthritis in comparison to placebo. Corticosteroids are one of the current standard of care options to treat knee osteoarthritis. Lipogems® is an FDA approved device for use in orthopaedics and arthroscopy procedures. You are being asked to participate because you have symptomatic osteoarthritis of the knee. Approximately 75 people will take part in this study at the University of New Mexico. Lipogems® will be donating kits for this study.

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things will happen: You will be enrolled in the study, which requires six activities: one procedure, two brief follow-up appointments, and three sets of online surveys. Upon enrollment, you will be randomized to receive one of three treatment options: Lipogems®, steroid injection, or placebo. Participants who are assigned to receive Lipogems® will know, because this procedure requires a lipoaspiration (fat tissue removal) from the abdomen followed by reinjection into your knee. Participants who are assigned to receive either a steroid injection or a placebo injection will not know whether they are getting a steroid or placebo until the end of the study. After you are assigned to a group, you will be scheduled for your procedure. At the procedure, you will fill out three surveys about the pain in your knee and how it affects your daily life and a medication log. You will then receive your injection. You will be scheduled for two follow-up appointments: six weeks later and six months later. You will be asked to complete the same three surveys at each follow-up visit. You will be emailed these same surveys and medication log again two weeks after your injection, three months after, and one year after. After completion of your one year questionnaire, you will be told what group you were assigned to. If you were assigned to receive placebo, you may elect to have a corticosteroid injection at this time. Your participation in the study will be complete after your one year follow-up visit.

Participation in this study will take a total of up to a maximum of eight hours over a period of one year.

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

Every effort will be made to protect the information you give us. However, there is a small risk of loss of privacy and/or confidentiality. Although a breach in patient confidentiality is unlikely to occur and should

not negatively impact your health or overall well-being, the necessary precautions will be taken to minimize this risk.
Otherwise, Intra-articular knee injections, such as corticosteroids and Lipogems®, are employed in routine clinical practice to treat knee osteoarthritis. With any injection, including steroid injections, there is a risk of local adverse reaction such as an allergic reaction, increased pain or swelling, and a risk of infection that may be deep in the joint and lead to septic arthritis. Other risks of steroid injections include a higher sugar concentration in your blood for up to 3 days, skin discoloration, thinning of the layer of fat cells under your skin, and facial flushing. Some patients have weakening of the tendons or ligaments that may lead to them breaking. In addition to an injection in the knee, Lipogems® involves a lipoaspiration procedure, which is the removal of fat cells like what is done during a liposuction, from the patient's stomach. Some risks of lipoaspiration include the development of a fluid pocket or collection of blood in the area that may need to be drained, infections, and changes to the skin such as a scar, an area of darker skin compared to the surrounding skin, or a small area of skin hardening. Very rarely, more serious complications may arise, including but not limited to irritation of skin tissues leading to death of the cells or a localized toxic reaction to the anesthetic medication that is used to make the stomach numb for the removal of fat cells.

How will my information be kept confidential?
Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed two years after data collection has ended for the entire study. Your paper documents will be shredded and disposed of, and any computerized files will be deleted. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by the investigators, federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

What are the benefits to being in this study?
There may or may not be direct benefit to you from being in this study. Some patients may experience reduced pain or increased joint functionality of the affected knee after injection. However, your participation may help find out which knee injection is the superior treatment for other patients with knee osteoarthritis.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate. You and your clinician can still discuss other options for treatment of your knee pain. There are a variety of different treatment options available to explore and the choice depends on your medical history, your desires, and your clinician's medical expertise. Some options include: NSAIDs (like aspirin or ibuprofen), steroid injections, other forms of injections that are not steroids, or a total knee replacement surgery. If you choose not to participate, your clinician will still review your medical history, your current complaints, and other medical information available to them to help you choose a treatment option.

Will I be paid for taking part in this study?

You will be compensated up to $80 via reloadable gift card for participating in the study. A $25 gift card will be distributed at each in-office follow-up visit and each completion of the online survey compensates $10.

What will happen if I am injured or become sick because I took part in this study?
If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost.

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the (505) 272-1129 for more information.

How will I know if you learn something new that may change my mind about participating?
You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your access to further healthcare.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: parts of your medical record, including results of physical exams, information about your osteoarthritis symptoms, and x-ray results obtained to evaluate your knee.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Dustin Richter, MD
MSC 10-5600
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Dustin Richter, MD, or his associates will be glad to answer them. Please call Leorrie Atencio Monday-Friday from 8-5pm at 505-272-3573. If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNMHSC and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

A description of this study 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 results. You can search this website at any time.

What are my rights as a research participant?
If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at
https://hsc.unm.edu/research/hrpo/**Consent and Authorization**
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this Consent Form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

_____	_____/_____	
Name of Adult Participant (print)	Signature of Adult Participant	Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____	_____/_____	
Name of Research Team Member	Signature of Research Team Member	Date