Glenohumeral Cortisone Injection

NCT04216017

Jonah Hebert-Davies

Consent Form

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UNIVERSITY OF WASHINGTON

CONSENT FORM

A Randomized Controlled Pilot Study Evaluating the Efficacy of Early Glenohumeral Triamcinolone (Cortisone) Injection in Patients with Shoulder Stiffness following Proximal Humerus Fractures

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24-hour emergency telephone number Investigator Call 206.744.3000

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

PURPOSE OF THE STUDY

After breaking the top of your upper arm bone some patients develop shoulder stiffness. The purpose of this project is to see if subjects who receive a cortisone (Kenalog-triamcinolone) injection get more shoulder motion back than patients who receive an injection of lidocaine. 20 people will be in the study with 10 receiving triamcinolone and 10 receiving lidocaine injections.

STUDY PROCEDURES

If you agree to be in this study you will be randomized (like the flip of a coin) to the control group or case group. Each group will receive 1 ultrasound guided injection. This is an intraarticular injection which means an injection into your shoulder joint. If you are in the control group you will be injected with 5 cc (about 1 teaspoon) of the drug lidocaine, 1%.you are in the case group you will be injected with 5 cc (about 1 teaspoon) that includes 4 cc of the drug triamcinolone, 40mg/cc (a steroid) together with 1 cc of the drug lidocaine, 1%."Study staff will not know which injection you receive. A radiologist will perform the injection which will take up to one hour. You will only have 1 injection as part of your participation in this study. You will also have a physical examination to look at your shoulder range of motion and we will ask you some questions. The physical exam and questions are part of your standard of care but information from the exam and questions will also be used for this research. The physical exam will take about 10 minutes and answering questions will take about 5 minutes.

The questions will be about your ability to perform certain activities and your pain. The most personal or sensitive question you will be asked is do you take pain killers.

You may refuse to answer any question.

Completing the physical exam and questions will be done 4 times over 6-months. The first time is when you sign this consent form and before you receive the injection. You will complete the physical exam and questions again 6, 12, and 26 weeks after you receive the injection.

We will review your medical records for clinical information related to your shoulder fracture during the course of your care.

RISKS, STRESS, OR DISCOMFORT

You may feel that there is a psycho-social risk, stress, discomfort, or potential for a breach of confidentiality, or the invasion of privacy that might result from completing questionnaires or having your medical record reviewed for information related to care of your injury.

There is a small risk of infection in the joint from either triamcinolone or lidocaine injection. There is also a small risk of allergic reaction from either the triamcinolone or the lidocaine injection. You may feel faint from the injection or feel pain at the site of injection. For the triamcinolone injection, there is a small risk of nerve damage, short term pain, and inflammation in the joint, tendon damage, loss of bone density (osteoporosis), death of nearby bone (osteonecrosis), an increase in blood pressure or a decrease in blood pressure, and a temporary increase in blood sugar. For the lidocaine injection, there is a small risk of drowsiness, agitation, lightheadedness, and a slight chance of significant cartilage damage (chondrolysis). There is a risk of bleeding from either injection.

”Any side effects will be handled by the person providing you the injection, your orthopedic surgeon or the emergency room as necessary You should contact the people listed on the top of this consent form in the event of study-related injury, illness, or distress.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to be part of this study you will be given our standard physical therapy prescription.

BENEFITS OF THE STUDY

It is possible that by participating in this study your stiff shoulder will have an increased range of motion.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support, from NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases), a Division of the National Institute of Health (NIH).

CONFIDENTIALITY OF RESEARCH INFORMATION

Your data will be kept confidential (linked to identifiers) All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish. There are some limits to this protection. We will voluntarily provide the information to: □ A member of the federal government who needs it in order to audit or evaluate the research; □ Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly; □ The federal Food and Drug Administration (FDA), if required by the FDA

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.

Your participation in this study will be noted in your UW medical record.

USE OF INFORMATION

The information collected as part of this research will not be used or distributed for future research studies.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Jonah Hebert Davies at 206.744.3000 right away. He will treat you or refer you for treatment.

"It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed at the top of this form. This number is monitored 24 hours a day." "If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility."

"The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your *proximal humerus fracture* or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you."

Printed name of study staff obtaining consent* Signature* Date*

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Subject