Title: EASiUR Trial: Efficient Anterior Shoulder Ultrasound Reduction Multicenter Prospective Randomized Trial

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Key Information for:

EASiUR Trial: Efficient Anterior Shoulder Ultrasound Reduction Multicenter Prospective Randomized Trial

Why is this research being done and what is involved?

- The purpose of the study is to determine if we can decrease the length of the emergency department visit and reduce patient exposure to x-rays by utilizing an ultrasound to diagnose and confirm reduction in shoulder dislocations.
- This study also seeks to determine if patients prefer ultrasound to x-ray when used to treat their shoulder dislocation.
- You will be randomly assigned to one of two groups. We will use either x-rays or ultrasound for the diagnosis and reduction confirmation of your shoulder dislocation.
- Your shoulder dislocation will be treated per standard of care.
- You will be asked to complete a short survey at the end of your visit.

Do I have to participate and what are the risks?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you are randomly assigned to the ultrasound group there will be no radiation exposure as compared to the x-ray group. You may or may not have other benefits from participating in the study. While the study is designed to randomize participants to a single group, it is possible that you may receive both an ultrasound and x-ray during your visit.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Dr. Jordan Tozer by calling the VCU Emergency Department, 804-828-5250 during business hours or 804-828-0999, during off hours.

Consent to Participate in Research

EASiUR Trial: Efficient Anterior Shoulder Ultrasound Reduction Multicenter Prospective Randomized Trial

Principal Investigator: Jordan Tozer, MD

Introduction to Research at Virginia Commonwealth University

Doctors, nurses, and medical researchers at VCU want to know more about the nature of disease and how to improve the lives of patients and their families. One way to learn more about diseases and their treatment is by asking patients to take part in research studies like this one, which is being led by Dr. Jordan Tozer.

You are being invited to participate in this research study. Before you agree to take part though, you need to know what to expect, what risks might be involved, what benefits you might gain, and your rights as a research participant. Please take your time and read the information in this document carefully. Ask questions about anything that is unclear to you and do not sign this form until you are sure that you understand what will happen to you as a subject in this study. If you decide to participate, you will be given a copy of this consent form to keep for your records.

Information about this Study

Why am I being asked to participate?

You are being asked to participate in this study because we suspect that you have an uncomplicated shoulder dislocation.

How many people are going to participate in this study?

This study will involve about 100 participants from VCU and more from other institutions.

Who is doing this study?

The study is being led by Dr. Jordan Tozer from the VCU Department of Emergency Medicine, with assistance from a team of researchers from the same department.

Who can be in this study?

Participants in this study are 18 or older, present the VCU Emergency Department for uncomplicated shoulder dislocations, and consent to being part of this study. Anyone who is sustained an injury that is considered trauma, is pregnant, incarcerated, unable to provide consent, or has a history of shoulder replacement in the affected shoulder will not be included in the study.

What is the purpose of this study? What are the investigators trying to find out?

The purpose of the study is to determine if using ultrasound to diagnosis and confirm reductions of shoulder dislocations impacts the length of an emergency department visit for this condition.

What will I have to do? What will happen to me during this study?

After consenting to this study, you will be assigned to one of two groups. You will either have an x-ray if you are assigned to the traditional care group; or an ultrasound of your shoulder if you are assigned to the experimental group. If you are diagnosed with a shoulder dislocation, it will be reduced as per standard of care. In order to confirm reduction of your dislocation you will have an x-ray or an ultrasound, depending on your assigned group. It is possible that you could receive an ultrasound *and* an x-ray if the ultrasound was not sufficient for diagnosis or if there is suspicion for additional injuries. People who consent to the research may receive an ultrasound they may not have gotten through standard care, however, no one who consents to the research will receive an X-ray they would not have otherwise received as part of the research. Ultrasound and X-rays may involve repositioning which could be slightly uncomfortable. Ultrasound use requires a small amount of gel to be put on your skin which can be cold. Finally, once your clinical treatment is complete you will be asked to complete a short survey regarding your experience during your visit. We will collect some information from your chart but nothing that identifies you individually.

How long will I be part of this study?

You will participate in this study while in the Emergency Department. No further participation is requested.

Information about the Possible Risks of Participating in the Study

It is important that you be aware of the following known risks associated with participating in this study:

- Increased time to diagnosis or treatment if both an ultrasound and x-ray need to be done
- Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you, though all traditional steps to mitigate this risk in compliance with IRB policies are being taken

- Ultrasound and X-rays may involve repositioning which could be slightly uncomfortable. Ultrasound use requires a small amount of gel to be put on your skin which can be cold.

It is not always possible to know all of the risks associated with a study like this one. If any new risks are discovered for this study, your doctor or someone from the study team will let you know so that you can make an informed decision regarding whether or not to continue participating.

Information about the Possible Benefits of Participating in this Study

There are no clearly defined direct benefits to you for participating in this study. The study may benefit future patients, however, because doctors will have greater knowledge of possible treatments for shoulder dislocations.

What if I Decide not to Participate?

Participation in this study is voluntary. If you do not wish to participate in the study, you will still receive the standard diagnostic and therapeutic care for your condition.

Can I Stop Taking Part in the Study Once I have Enrolled?

You may withdraw from the study at any time, without any penalty to you. You will still receive treatment for your condition if you decide to stop being in the study.

If your doctor feels that your continued participation in the study is not in your best interest you may be taken off the study without your consent. Your doctor will let you know if it necessary to take you off the study.

In order to withdraw, please contact the principal investigator at the following address:

Dr. Jordan Tozer
c/o EASiUR Trial
VCU Health Department Of Emergency Medicine
1250 E. Marshall St
Box 980401
Richmond, VA 23298-0401

Confidentiality of Personal Information

How will my personal information be kept confidential?

Your study data will be stored securely at the VCU Department of Emergency Medicine. Your paper data, including this consent, will be kept in a locked research file that only the PI and the study team can access. Electronic data will be kept on secure VCU servers that are password protected.

If the Principal Investigator and/or the sponsor decide to report study results in research articles or scientific presentations, no personal information about you will be revealed. The information collected about all of the study participants is grouped together without any way of identifying individuals from within that group. If the articles or presentations include your x-rays, photographs, or other images gathered during the study, it will not be possible for anyone to identify or recognize you from those pictures and your identity will not be revealed.

Who will know that I am participating in this study?

Every effort will be made to protect your privacy and maintain the confidentiality of your medical records during this study. From time to time, though, it might be necessary for certain people to check parts of your medical record to make sure that the study data are correct and complete. Whenever such checks are made, only study data is recorded, not any personal or unrelated medical information about you. The only people who may have access to your study data are the lead investigator and study staff, auditors from the government agencies that oversee medical research, and the VCU Institutional Review Board staff (the committee that oversees research involving human subjects).

In general, you will not receive any results specific to your care from this study. 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 Website will include a summary of the results. You can search this Web site at any time.

In general, we will not give you any individual results from the study.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

What will it Cost to Participate in this Study?

You are not responsible for any additional costs related to the research study that are above the cost of your routine care.

Will I be Paid to take part in this Study?

You will not be paid for taking part in this study.

What happens if I am injured or become sick because I took part in this study?

If you are injured by, or become ill, from participating in this study, please contact the study doctor immediately. Medical treatment is available at VCU Health System. Your study doctor will arrange for short-term emergency care at VCU Health System or a referral if it is needed.

Fee for such treatment may be billed to you or to appropriate third party insurance. Your insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

Your Rights as a Participant in this Research Study

Anyone who volunteers to participate in a research study is entitled to certain protections under federal law. The federal regulations make sure that you are willingly and voluntarily participating, that you have not been forced or pressured to take part, that any potential risks have been explained to you, that any potential risks to you are minimized, that you have been informed of possible benefits of being in the study, that you can leave the study at any time without penalty, and that you have been given enough information to make a decision about whether or not to take part in the study.

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Dr. Jordan Tozer
Jordan.tozer@vcuhealth.org
c/o EASiUR Trial
VCU Health Department Of Emergency Medicine
1250 E. Marshall St
Box 980401
Richmond, VA 23298-0401

and/or

Dr. Jacob Wayman
Jacob.wayman@vcuhealth.org
c/o EASiUR Trial
VCU Health Department Of Emergency Medicine
1250 E. Marshall St
Box 980401
Richmond, VA 23298-0401

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Please understand that by signing this consent form you do not give up any of your legal rights, but indicate that you have been informed about the research study in which you are agreeing to participate. A copy of this signed consent form will be provided to you for your records.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

Complete health record	Diagnosis & treatment codes	Discharge summary
History and physical exam	Consultation reports	Progress notes
	X-ray reports	X-ray films / images

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Data Coordinators
- Institutional Review Boards
- Research Collaborators
- Government/Health Agencies
- Data Safety Monitoring Boards
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator:

Dr. Jordan Tozer
Jordan.tozer@vcuhealth.org
c/o EASiUR Trial
VCU Health Department Of Emergency Medicine
1250 E. Marshall St
Box 980401
Richmond, VA 23298-0401

Informed Consent Statement

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

____
Subject Date and Time

____
Printed name of Subject

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

____
Signature of Person Obtaining Consent Date and Time

____
Printed name of Person Obtaining Consent

____

Signature of Principal Investigator Date and Time

____

Printed name of Principal Investigator

Distribution of Copies of signed consent:
1 copy to subject, 1 copy placed on medical chart, 1 copy in study coordinator/investigator records.