Bayesian Non-inferiority Trial of Injection Therapies for Acromioclavicular Joint Pain: a Randomized Clinical Trial

NCT05161468

12 AUG 2022

MADIGAN ARMY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Meets 2018 Common Rule Requirements

PRINCIPAL INVESTIGATOR: Jeremy Schroeder, DO

KEY INFORMATION FOR PROTOCOL: Comparative effectiveness of injection therapies for acromioclavicular joint pain: a randomized clinical trial

You may be eligible to take part in this research study. This form gives you important information about the study.

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. If you have questions later, the contact information for the research investigator is below. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

You do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty. Your decision will not affect your future care at Madigan Army Medical Center or any other medical clinic where you are already authorized to receive care.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

You are being asked to take part in this research study because you are seeking care for your shoulder pain. By doing this study, we hope to learn more about which injection therapies (Platelet Rich Plasma, Lidocaine, or Corticosteroid) might be more effective for the management of this type of shoulder pain. All three of these therapies are FDA-approved and their use in the study will be consistent with the labeling indications. Your participation in this research will last about one year.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

The possible benefits to you as a participant in this research study are that you may receive relief and experience improvement in your shoulder pain. However, there is no guarantee that you will get better or benefit from being in this research. The researchers

hope the information learned may help providers better manage patients with shoulder pain in the future.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

If you choose to take part in this study: the risks for this study are minimal.

All of the treatments that are being evaluated as part of this study are standard of care, meaning you could receive any of them even if you were not a participating in this study. Medical providers use these treatments and others based on their personal preference for what they think might be most appropriate. Due to randomization, you may or may not receive the same treatment plan that you might have received if you were not in the study. You will always be able to discuss your individual situation with the physician delivering treatment or your primary care provider at any time during the study and can always opt for a different treatment after discussing it with your primary care provider.

A licensed clinician (in most cases, a physician) will be giving you the injections. The risks that accompany an injection include increased soreness at the injection site, possible infection, allergic reaction, and potential changes in skin pigmentation. Local soreness is the most common side effect; infection, allergic reactions, and changes in pigmentation occur in less than 1% of cases.

Some of the questions asked may make you uncomfortable. You can choose to skip or not answer any questions.

You may have a bruise or experience soreness at the site where blood is drawn. There is also a slight possibility of infection at the site where blood is drawn.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to personal information in your records stored by the research team.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have at Madigan Army Medical Center if you choose not to volunteer. Alternative treatments and/or procedures that may be available to you include: self-management strategies and seeing other medical providers. You should talk with your personal primary care provider (if applicable) about these options.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Jeremy Schroeder, DO. If you have questions, suggestions or concerns about the study, his contact information is 253-968-2077 and mailing address: Madigan Army Medical Center, Department of Family Medicine, 9040 Jackson Avenue, Tacoma, WA 98431.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the Madigan Army Medical Center IRB Office at: 253-968-0149, Madigan Army Medical Center, Department of Clinical Investigation, 9040 Jackson, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research study, of any kind.

If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

DETAILED CONSENT:

1. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are seeking care for your shoulder pain. The purpose of this study is to learn about which injection therapies might be more effective for the management of this type of shoulder pain. Your participation in the study may last up to one year.

There will be about 150 people taking part in this study from all participating sites.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, we need to confirm that you qualify for the study. Some of the information needed may be collected from your medical record. We may also conduct an additional exam and ask you questions about your medical history and current health.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you are eligible to participate in the study, you will be randomly assigned to one of three groups. Randomization is a process like flipping a coin and means you will have a 33.3% chance of being assigned to any of the three groups.

Each of the three groups involve the same type of care that you could receive from medical providers even if you don't participate in the study. We are interested in understanding how the different injections compare to each other, to see if one works better than another, and how effective they can be in the long term. These options include three different types of injection therapies, all of which are injected into one of the joints in your shoulder that is causing you pain (acromioclavicular joint).

- Group I – Platelet rich plasma injection: a concentration of the platelets from your own blood plasma used to help maximize the healing in your joint. Plasma has certain proteins and molecules that are thought to promote healing. Your own blood will be extracted, spun in a centrifuge to isolate the platelets, and then concentrated in a solution that will be injected into the injury site.
- Group II – Corticosteroid injection: a steroid injected at the injury site, which helps primarily by reducing the immune system response that creates inflammation after an injury. The steroid fights inflammation associated with an injury, and by doing so, is able to reduce pain.
- Group III – Lidocaine injection: an anesthetic that blocks pain signals and in turn helps to reduce pain.

This is a single blind study, which means you will not know exactly which of these three injections you are receiving. You will be told which study injection you received

at the end of your 12-month follow-up visit. You will also have blood drawn (approximately 6 tsp / 30 mL) prior to your injection by a credentialed clinical staff member or research associate.

You may receive your first injection today, but if not, then you will be scheduled to return to the clinic within the next few days. In many cases, one injection is all that is needed, but you may receive up to 4 injections during the course of the next 12 months based on how you respond to the first injections. You will follow-up with the study physician between 2-10 weeks after your first injection to discuss whether another injection would be beneficial. Additional return visits will be scheduled for you if needed.

You will be contacted by your preferred method (i.e., in person, email, phone, text, mail) to answer a few questions (we estimate less than 5 minutes) every month, for the first 6 months. This will help us understand how quickly you are improving, and we would really appreciate your honest feedback with each of these, even if you are not getting better (or feeling worse). If you have an in-person follow-up visit, we ask that you please not discuss what type of injection you think you may have received with the research staff. This is to ensure that the research staff remains blinded to the type of treatment you have received.

Finally, we will ask you to follow-up with the research team at approximately 2 months, 6 months, and 1 year from your initial enrollment to answer some questions in addition to those you are answering monthly. Follow-ups can be conducted in person, electronically via a data collection web service, or by regular mail. We estimate it will take approximately 5 to 20 minutes to fill out the questionnaires. Some of this data might already be available if you filled it out for other reasons (in other clinics). If we are able to access it, then we will not have you fill it out again. To ensure your follow-up visits are completed in a timely manner, we will send reminder notices over mail, email, phone, and or text message, whichever you prefer. These follow-up visits will allow us to understand how your symptoms and quality of life changes over time.

We will also review your medical records from all care that you received in the TRICARE medical database, which tracks and stores health care for DoD beneficiaries. This will include the year leading up to your enrollment, while you are enrolled in the study, and for one year after you complete the study. We will collect this data so that we can evaluate the care you received for your shoulder pain (for example, information about your prescriptions for pain medications, visits to other providers, number and types of X-rays and MRIs, etc.). This will help us understand how different treatment decisions might be influencing your progress. If you are an active-duty soldier, we will also review the number of limited duty days you had that were related to your shoulder pain during the year before and after your enrollment in the study.

4. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for the treatment of your shoulder pain. Alternative treatments and/or procedures that may be available to you include: self-

management strategies and seeing other medical providers. You should talk with your personal primary care provider (if applicable) about these options.

Choosing not to take part in this research study is also an option.

5. **IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?**
No, you will not receive any compensation for participating in this study.

6. **ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?**
No, there are no costs to you for taking part in this research study.

7. **PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):**

Principal Investigator: Jeremy Schroeder, DO
Phone: 253-968-2077
Mailing Address: Madigan Army Medical Center, Dept of Family Medicine, 9040 Jackson Ave., Tacoma, WA 98431

8. **STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):**

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your coded/de-identified research data.

The Department of Defense (DoD) Defense Health Agency (DHA) is providing funding for this study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

9. **SOURCE OF FUNDING:** Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

10. **LOCATION OF THE RESEARCH:** Madigan Army Medical Center

11. **DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**: The study team foes not have any conflict of interests related to financial sponsors.

12. **WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?**

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the

records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. In addition to the team of researchers, these records may be looked at by staff from the Madigan Army Medical Center HRPO office, members of the Madigan Army Medical Center Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: any paper copies of study files will be stored in a locked cabinet in a locked room. Electronic copies of your data will be stored in encrypted password-protected files on secure encrypted computers. The consent form that identifies you by name will be stored in a locked cabinet. All research materials will be coded with a unique identifier (not your DoD ID) to protect your identity. The data file linking your name and code number will be accessible only to the researchers that work within DoD, and your data will be entered into a computer file by this code number. If your data is used in scholarly presentations or journal articles, the investigators will protect your anonymity by reporting only aggregate data (e.g., group means) where appropriate.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will never be personally identified; all information will be presented as anonymous data.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Those listed above will have access to your records and agree to safeguard your protected health information (only research members within DoD) by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

In some cases, we will use 3rd party services to communicate by text message and/or email with you (i.e., to send questionnaires or communication), as we disclosed earlier in this consent form. This means that we may have to enter your name, email address, and phone number into 3rd party platforms. Your information will only be placed within accounts that belong to the research team and that only the research team has authorized access to; however, it will be kept in the storage maintained by the 3rd party service and subject to their security policies. This information will never include other personal health or private information. Even after you agree here with us, you may have to opt in again by each individual service

once we input you into the system. You may decline us contacting you by any of these means: contacting your cell phone (i.e., communication/questionnaires via text messages) and email (i.e., communication/questionnaires). In this case you would need to come in person to fill out electronic or paper forms in person. You can always opt out in the future if you change your mind by notifying the Primary Investigator in writing (see contact information below).

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept by the study team and MIRROR/USU indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

13. <u>AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH:</u> You are being asked for permission to use and disclose your protected health information (PHI) for this research study. Protected health information is defined as individually identifiable health information.

The Health Insurance Portability & Accountability Act of 1996, Public Law 104-191 (also known as HIPAA), establishes privacy standards to protect your health information. This law requires the researchers to obtain your authorization (by signing this document) before they use or disclose your protected health information for research purposes in the study listed above.

WHAT PERSONAL IDENTIFIERS AND/OR PROTECTED HEALTH INFORMATION (PHI) MAY BE USED AND DISCLOSED IN THIS RESEARCH?

The identifiers and/or PHI collected, used, or disclosed are below:

Identifiers:	Health information collected from you or your medical record:
Name	*Medical history*
Address	*Surgical history*
Dates (follow-ups, age)	*Laboratory results*
Phone numbers	*Imaging results (x-rays, MRIs, etc.)*
E-mail addresses	*Medications provided to you for your shoulder pain*
DoD ID Numbers	*Responses to your study questionnaires*
	Health information collected about your shoulder pain treatments while you are in the study

HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

You are being asked for permission to use or disclose your protected health information for research purposes in the research study entitled: Comparative effectiveness of injection therapies for acromioclavicular joint pain: a randomized clinical trial.

We are interested in looking at the effects of three different treatments for the management of your shoulder pain. In order to assess the benefit of these treatments, we would also like to evaluate the type and amount of healthcare that is utilized related to your shoulder pain 1 year prior to and 1 year after the date you enroll into this study. This includes the information listed below – x-rays, MRIs, medications, visits to other providers, etc. We are looking at the healthcare you have utilized 1 year prior to this visit in order to better understand the type of care you have received that led up to this visit. All of this information is collected from electronic health records that are stored on a Department of Defense database. In order to request access to any of the information in this database, our request has to be approved by the Institutional Review Board at Madigan Army Medical Center and then also by the privacy board at the Defense Health Agency. We use your name and DoD ID to request this data, however they return all the actual data in a de-identified manner. They do this by replacing your DoD ID with a unique ID (completely unassociated number). The data they return does not have any other potentially identifying information such as birthday, name, or sponsor DoD ID. Our analysis and our report of the data we collect will always be done with de-identified information. Your medical and surgical history is used to make sure you are able to participate

The use and disclosure of your protected health information is necessary in order to be able to conduct the research described. Records of your participation in this research may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 CFR 160 & 164).

Note: Protected health information of military service members may be used or disclosed without your authorization to military command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

WITH WHOM MAY YOUR PROTECTED HEALTH INFORMATION BE SHARED THROUGH THIS RESEARCH?

- The Madigan Army Medical Center Institutional Review Board
- Madigan Army Medical Center or Department of Defense representatives
- State and Federal Government representatives, when required by law (such as the Food and Drug Administration (FDA))

Those listed above who are covered entities under HIPAA agree to safeguard your protected health information by using and disclosing it only as permitted by you in this Authorization or as directed by state and federal law.

You need to be aware that some parties receiving your protected health information may not have the same obligations to safeguard your protected health information and may re-disclose your protected health information to parties not named above.

If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

You do not have to sign this document. If you decide not to sign this document:

- It will NOT affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research.

After signing this document, you can change your mind and:

- Notify the principal investigator in writing that you have withdrawn your permission to disclose or use your protected health information (revoke the Authorization).
- Send your written letter to Dr. Jeremy Schroeder, Madigan Army Medical Center, Department of Family Medicine, 9040 Jackson Avenue, Tacoma, WA 98431 to inform him of your decision. Your revocation is not effective until your letter is received.
- Researchers may continue to use and disclose your PHI that was obtained before your revocation became effective to the extent that the researchers have taken action in reliance on your earlier authorization. Researchers may also continue to use or disclose your PHI as necessary to maintain the integrity or reliability of the current research, as, for example, to account for your withdrawal from the study, to conduct misconduct investigations, or to report adverse events.
- If you withdraw the Authorization, you will not be allowed to continue to participate in the research.

During your participation in this research, you will not be able to access your research records. This is done to ensure the research results are reliable. After the completion of the research, you have the right to see or copy your research records related to the research listed above. A request for access must be made in writing to Dr. Jeremy Schroeder, Madigan Army Medical Center, Department of Family Medicine, 9040 Jackson Avenue, Tacoma, WA 98431.

If you have not already received a copy of the brochure entitled “Military Health System Notice of Privacy Practices,” you may request one, or it is available on-line at: https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/HIPAA-Compliance-within-the-MHS/Notice-of-Privacy-Practices

If you have any questions or concerns about your privacy rights, you should contact the MAMC Privacy Officer at phone number 253-968-1642.

This Authorization does not have an expiration date.

Your signature at the end of this document acknowledges that you authorize Brooke Army Medical Center and the members of this research team to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

14. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, your request must be made in writing to Dr. Jeremy Schroeder, Madigan Army Medical Center, Department of Family Medicine, 9040 Jackson Avenue, Tacoma, WA 98431. If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Your condition will continue to be treated in accordance with acceptable standards of medical treatment. Contact your personal physician to discuss medical treatment for your condition. You may be asked if you wish to provide further data collection from routine medical care. The data collected prior to your withdrawal, and the healthcare utilization data from medical records, will still remain part of the study database and will not be removed, unless you also ask for it to be removed.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

16. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

CONTACT INFORMATION:

Principal Investigator (PI): The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.
Principal Investigator: Jeremy Schroeder, DO
Phone: 253-968-2077
Mailing Address: Madigan Army Medical Center, Dept of Family Medicine, 9040 Jackson Avenue, Tacoma, WA 98431

Human Research Protection Program (HRPP) Office: The local Madigan Human Research Protection Program Office staff and/or Human Protections Director (HPD) will

be available to answer questions or discuss concerns you may have about this research study phone:253-968-0149, Department of Clinical Investigation, 9040 Jackson, Tacoma, WA 98431-1100.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information have been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

IRB NUMBER: 221073
IRB APPROVAL DATE: 08/12/2022
IRB EXPIRATION DATE: 08/10/2023