

Cover Page: Informed Consent

Official Title: Trigger Point Injection for Myofascial Pain Syndrome in the Low Back (T-PIMPS)

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

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Meets 2018 Common Rule Requirements

PRINCIPAL INVESTIGATOR: [REDACTED], MD, 9040 Fitzsimmons Dr., Tacoma, WA 98433, 253-968-1390

KEY INFORMATION FOR PROTOCOL: T-PIMPS (Trigger Point Injection for Myofascial Pain Syndrome in the Low Back)

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. Detailed information follows this page.

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

You are being asked to take part in this research study because you have low back pain determined to be consistent with myofascial pain syndrome (pain from the muscle and soft tissues). This study will look at three different treatments for low back pain and try to determine whether “trigger point injections” decrease both acute low back pain and acute-on-chronic low back pain when added to current therapies.

Your treatment will be selected by chance, you have a one in three chance of receiving (1) standard of care, (2) standard of care plus an injection of a medication called bupivacaine, or (3) standard of care plus an injection of normal saline (placebo). Researchers are also interested in determining which treatment helps improve your ability to walk and perform other daily functions.

Study participation will be during your entire Emergency Department stay and will include one phone call at 60-72 hours following your visit.

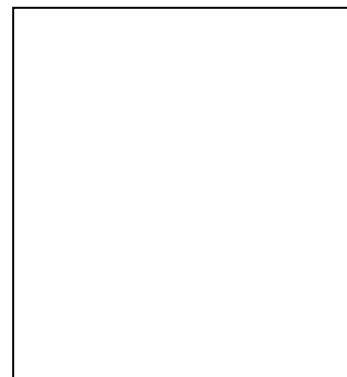
WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

This study may or may not benefit you directly, however, your participation may help to develop a treatment for low back pain that helps increase speed of recovery.

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

You should not take part in this study if you have had an allergic reaction to local anesthetics in the past. You may also experience pain at the injection site along with possible side effects of the medication/saline. There is also risk of injury to structures surrounding the injection site, however this is rare. You may also be concerned about your treatment being selected by chance, and not knowing which medication you are to receive.

Your alternative to participation would be to not to enroll in the study and receive the current standard of care and selection of medications at the discretion of your Emergency Provider.



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.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is [REDACTED]. If you have questions, suggestions or concerns about the study, his contact information is: [REDACTED], and mailing address: 9040 Jackson Avenue, Tacoma, WA 98431.

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the RHC-P IRB Office at: [REDACTED], Department of Clinical Investigation, 9040 Jackson, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research 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 in all sections of the consent form, including the risks and possible benefits to you.

DETAILED CONSENT:

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

The purpose of this research study is to learn about the role of trigger points in acute low back pain and to determine if injections of normal saline (salt water) or local anesthetics like bupivacaine can help decrease the amount of pain that people have when they develop low back pain from this cause. We suspect that injection of these trigger points (areas of muscle spasm) may improve low back pain, and that by breaking the pain-spasm cycle, patients may get some relief from their pain in addition to the usual pain medications used for low back pain.

There will be about 150 people taking part in the study at Madigan Army Medical Center over a period of 2 years.

You will also be asked to provide information about your pain and functional ability, in addition to information about your baseline health. Researchers will also need your contact information to follow up with you about your back pain within 60-72 hours following your Emergency Department visit.

Study participation does not prevent you from returning to the Emergency Department for further care should symptoms worsen or if you have other medical concerns.

This research study involves a drug called bupivacaine, which has not yet been approved or cleared by the Food & Drug Administration (FDA) for the treatment of myofascial pain syndrome or trigger point injections; however, the FDA has not objected to its use in this research study to learn more about its safety and/or effectiveness. This drug has been approved by the FDA for peripheral nerve blocks, infiltration of local anesthetic, and epidural blocks.

Normal saline (placebo) likewise is commonly used in fluid resuscitation, but is only FDA approved for bladder irrigation, nasal spray and chloride replacement.

This study is looking at trigger point injections. Trigger point injections have been well studied in the outpatient setting, but have not been well-researched for acute low back pain. This means that trigger point injections are considered an experimental procedure for the treatment of myofascial pain syndrome in low back pain.

At the end of this research study the clinical results, including research results about you will be shared with you if you wish to know the study results. In order to receive the results of this study when it is complete, please email the primary investigator.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

You will already have been pre-screened so that the researchers can confirm that you qualify for the study. Part 2 of the screening process occurred during your evaluation by your provider for your low back pain. They should review the inclusion and exclusion criteria for the study with you.

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

If you meet inclusion criteria and consent to participate by signing this consent form, researchers will collect information about your pain, duration of pain, demographic information and functional status.

You will then be randomly assigned to one of the three treatment groups. Randomization is a selection process like flipping a coin and means you will have a 1 in 3 chance of being assigned to one of the treatment groups. You will receive standard of care regardless of your group assignment. The groups are as described below.

Standard of Care Group

- Tylenol, 650 mg every 4 hours by mouth,
- Ketorolac, 15 mg intramuscular injection (in the Emergency Department),
- Ibuprofen, 400 mg every 4 hours by mouth (when you go home),
- Flexeril, 10 mg once nightly (when you go home), and
- Stretching exercises and warm heat packs.

Trigger Point Injection with Normal Saline (salt water) Placebo Group

This group will receive the **standard of care** as outline above **plus** up to 8 ml of normal saline injection intramuscularly (2 ml/ trigger point).

Trigger Point Injection with 0.5% Bupivacaine (local anesthetic) Group

This group will receive the **standard of care** as outline above **plus** up to 8 ml of 0.5% bupivacaine injected intramuscularly (2 ml/ trigger point).

You will have a one in 3 chance of being in the placebo group (Trigger Point Injection with Normal Saline). A placebo is an inactive, harmless substance, like a normal saline that looks like the research study medication but contains no active ingredients.

A Post-Intervention Survey will be filled out 30-60 minutes following the injections or when you consented to participate in the study.

You will receive a phone call 60-72 hours after your Emergency Department visit from a study team member asking about your pain and functionality. These will be the same questions asked in the Post-Intervention Survey in the Emergency Department.

This research study is a double blind study, which means that neither you nor the research team will know whether you are receiving the research study medication or a placebo. In the event of an emergency, there is a way to find out which one you are receiving.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of physical discomfort and soreness from injections. Most patients have a sharp pinprick sensation with injections and a burning sensation which is temporary when using local anesthetic. Other rare risks include injury to surrounding structures and subsequent complications such as pneumothorax (air in the space outside of the lungs), infection, injury to blood vessels or toxicity from the medications used. All of these complications however are small and occurrence of these is very infrequent. There are no anticipated psychological, legal, social or economic risks associated with this study.

Drug Risks - Bupivacaine- Potential but rare side effects of bupivacaine

- Arrhythmias, heart block, cardiac arrest and death with intravascular use including in pregnant females
- Methemoglobinemia leading to shortness of breath
- Respiratory arrest
- Seizures
- Local Anesthetic Systemic Toxicity (LAST)- contributes to all of the above when doses exceed maximum dose
- Septic meningitis

Bupivacaine- Less harmful side effects include:

- Anesthesia/ paresthesias around injection site
- Loss of motor function in multiple areas of the body
- Slow heart rate
- Dizziness
- Headache
- Blurred vision
- Ringing in the ears

Bupivacaine is advised to have a dose reduction in elderly patients, acutely ill patients and is not recommended for obstetric anesthesia due to risk of cardiac death.

Drug Interactions with bupivacaine:

- Anti-hypertensive medications, atypical anti-psychotics and anti-parkinsonian medications can lead to low blood pressure
- Medications like metoclopramide, nitrofurantoin, and nitrates may potentiate methemoglobinemia
- Allergic Reaction: Patients who have had allergic reactions to other local anesthetics in the past should not take this medication. Signs include difficulty breathing, rash, hives, rapid heart rate, swelling of lips or throat, abdominal pain or diarrhea. You will be monitored in the Emergency Department for any signs or symptoms of this.

Normal Saline - Potential side effects of normal saline

- Irritation to surrounding tissue/ soreness
- Other side effects if used intravenously in large amounts, but it is not being used in this manner in this study.

You may have a bruise or be sore at the site where injections are performed.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There may also be other risks of taking part in this study that we do not yet know about.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

Besides potential improvement of your low back pain, there are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others are contribution to development of a new treatment for low back pain which could benefit millions of people who present with low back pain to the Emergency Department every year. In addition, the military may benefit from this treatment in allowing soldiers to have a quicker return to duty after injuries leading to low back pain.

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

There may be other options for treating your low back pain with trigger points. Alternative treatments and/or procedures that may be available to you include:

- Lidoderm patches,
- massage (not available in the Emergency Department),
- freeze spray with massage (not performed in ED),
- acupuncture (not performed in ED) and
- dry needling (not performed in the ED).

In addition, you could choose to have standard therapy with substitution of any of those medications for other similar medications.

Opioid medications are sometimes used for low back pain, but require discussion and approval by your physician. You should talk with your personal physician about the options not available in the Emergency Department, and may speak with your Emergency provider about the options available in the Emergency Department.

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

The medications involved in this research study may also be available through your personal physician without taking part in this study.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study): [REDACTED]

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data): Sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

11. SOURCE OF FUNDING: None

12. LOCATION OF THE RESEARCH: Madigan Army Medical Center

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS: No study team members have any financial disclosures or interests that relate to this study.

14. 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. These records may be looked at by staff from the Department of Emergency Medicine at the Madigan Army Medical Center, the 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: filing paperwork in locked boxes available only to team members participating in the study, separating contact information from provided information by the patient, and storage of the data on a password encrypted website in the Madigan Portal. All other information provided by the patient will be de-identified.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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 results. You can search this Web site at any time.

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.

The research study team will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data

15. AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH: 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:

<ul style="list-style-type: none">• Names• Dates (except year) directly related to an individual such as birth date	<ul style="list-style-type: none">• Phone numbers
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HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

The above information including your name and phone number will be used to contact you 60-72 hours after treatment in the Emergency Department to obtain follow up information about your symptoms. Your age, medical history, surgical history, medications at baseline and history of preceding injuries will be used to make sure that treatment groups are equal and in order to analyze whether trigger points are or are not effective in treating low back pain in certain groups of people.

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.

By signing this document, you give your permission for information gained from your participation in this research to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

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

- The Regional Health Command - Pacific 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 [REDACTED], at Madigan Army Medical Center, 9040 Jackson Ave, Tacoma, WA 98431 to inform him of your decision [REDACTED]. 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 [REDACTED], 9040 Jackson Ave, Tacoma 98431. [REDACTED].

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 HIPAA Privacy Officer, 9040 Jackson Ave, Tacoma, WA, 98431. Telephone: 253-968-1390.

This Authorization does not have an expiration date.

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

16. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

An incidental finding may cause you to feel anxious. Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

If you decide that you would prefer not to know about any incidental findings, mail a request to [REDACTED], Madigan Army Medical Center, 9040 Jackson Ave, Tacoma, WA, 98431. Telephone: [REDACTED].

17. 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.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the study Primary investigator (PI) [REDACTED], in writing at ATTN: [REDACTED] - Department of Emergency Medicine, Madigan Army Medical Center, 9040 Jackson Ave, Tacoma, WA 98431 (phone # [REDACTED]). If you do not follow these procedures, you may be contacted at the expected interval to follow up on your pain after your Emergency Department visit. If you decide to no longer participate in this research study, the researcher will not collect any further information from you.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

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.

The sponsor of this research study may terminate the research study and/or your participation in this research study for safety reasons or if the drug receives the approval of the US Food and Drug Administration. There is no guarantee that the drug you will receive during this research study will continue to be available through the military health system.

19. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to,

free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

20. 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: [REDACTED],

Phone: [REDACTED]

Mailing Address: ATTN: [REDACTED] - Department of Emergency Medicine, Madigan Army Medical Center, 9040 Jackson Ave, Tacoma, WA 98431

Madigan Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office staff and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study. Please contact the Madigan HRPP Office at: 253-968- 0147, 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 has 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

