Intracutaneous Sterile Water Injections for Acute Low Back Pain in the Emergency Department: a Pilot Study

NCT04240483

24 March 2020

Volunteer Name:	

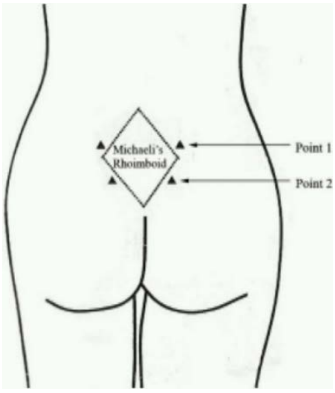
99TH MEDICAL GROUP
INFORMED CONSENT DOCUMENT

Title of Protocol:	Intracutaneous sterile water injections for acute low back pain in the Emergency Department: a pilot study.
FWH #:	FWH20200050H

KEY INFORMATION ABOUT STUDY PARTICIPATION: You are being asked to consider participation in this research study because you are aged 18 to 64 years old and presenting to the Emergency Medicine Department with complaints of back pain lasting less than 2 weeks. The purpose of this study is to see if intracutaneous sterile water injections are an effective treatment for low back pain. Once you are deemed eligible to participate, you will be randomized (like flipping a coin) into either the experimental or control group. The experimental group will receive intracutaneous sterile water injections and the control group will receive intracutaneous dry injections. We will gather information from your injection and assess your pain before, during, and after the procedure using a Visual Analogue Scale. We will also ask you to assess your overall satisfaction.

A Visual Analogue Scale is a visual scale to help assess the severity of your pain. You will make a mark on a line to represent your pain level, lowest being “No Pain”, the middle being “Moderate Pain”, and the highest being “Worst Pain.”

Intracutaneous sterile water injections involve a small amount of sterile water that is injected under the skin at 4 different locations on the lower back. We will identify and mark four points on your lower back. We will then thoroughly clean the area. A small amount of sterile water will be injected just beneath the skin in the 4 marked locations. This will leave a small blister at each site which may sting for approximately 20-30 seconds. Intracutaneous dry injections involve the same procedure, however, the syringe will be empty and no sterile water or other substances will be injected into the sites. It is important that you do not rub or touch the injection sites for 30 minutes after.



Risks associated with getting the intracutaneous sterile water injections and the dry injections in this study include pain, bleeding, feeling light-headed, bruising at the injection site, and infection. There is also a risk of inadvertent breach of confidentiality.

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24 Mar 20
Date ICD
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INFORMATION ABOUT THIS CONSENT FORM: You may be eligible to take part in a research pilot study. This form gives you important information about the study. You may be asked to sign your name in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers and ask any questions you may have about the study. You may also wish to talk to your friends, family, or a doctor about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the purpose and procedures of the study, including risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION: Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before the study is completed, your decision will not affect your eligibility for care or any other benefits to which you are entitled as a DoD beneficiary. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

PRINCIPAL INVESTIGATOR: The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	Rank:	Branch:	Department and Base:
Lindsey Schmelzer, EMPA Resident	Maj	USAF	Emergency Medicine, 99MDG

PURPOSE OF THIS STUDY (Why is this study being done?)**:** You are being asked to consider participation in a research study because you are aged 18 to 64 years old and presenting to the Emergency Medicine Department with complaints of back pain lasting less than 2 weeks. The purpose of this study is to see if intracutaneous sterile water injections is an effective treatment for low back pain. This study will enroll approximately 40 subjects overall.

PROCEDURES: If you decide to take part in this research study, you will be asked to sign this consent form. During your participation in this study, you will meet with Maj Lindsey Schmelzer, the Principal Investigator (PI), or an alternative study staff member. As a research participant, you will undergo the following procedures:

Screening Visit: [Research-Related]

- Obtain your signed Informed Consent Document and HIPAA Authorization.
- We will ask you to complete the Visual Analogue Scale (VAS) to record your current pain level.
- We will ask you to provide your contact and demographic information and your occupation.
- We will ask you to provide information on any injections, surgeries, implants or other invasive spine therapies.
- We will have you list your current medications, and any past medical history/diagnoses including the duration of your low back pain.
- We will withhold any alternative interventions until you have completed the final pain and patient satisfaction scales, approximately 30 minutes following injection. (See "Risks or Discomforts" below for more details)

Assignment to Study Groups [Research-Related]: When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to 1 of 2 study groups. You will not know what group you have been assigned to until after you have completed this study.

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- Group 1: Intracutaneous sterile water injections
- Group 2: Intracutaneous dry injections

Study Intervention Visit: [Research-Related]

- We will ask you to complete the VAS before your injection.
- The study intervention will be performed.
- We will ask you to complete the VAS 10 minutes after the injection.
- We will ask you to complete the VAS 30 minutes after the injection.
- We will ask you to indicate your overall patient satisfaction 30 minutes after the injection.
- We will record information regarding any other standard of care treatments/interventions provided throughout your Emergency Department visit.

RISKS OR DISCOMFORTS: The investigators have designed this study to learn if intracutaneous sterile water injections is an effective treatment for low back pain. To limit confounding factors, you will not receive any alternative medications or traditional "standard of care" interventions until you have completed the final pain and patient satisfaction scales approximately 30 minutes following the injections. If your pain is severe or new symptoms develop prior to completion of the final pain and patient satisfaction scales, please let the study staff know immediately.

Additionally, there are risks to taking part in this research study. One risk is that you may have side effects while on this study. Everyone taking part in this study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately about any side effect that you have while taking part in this study. For more information about risks and side effects, ask one of the researcher or study staff. The risks associated with getting the intracutaneous sterile water injections and the dry injections include:

Likely and Not Serious:

- Pain
- Bleeding
- Feeling light-headed
- Bruising at the injection site
- Infection

There may be a risk of inadvertent breach of confidentiality.

WITHDRAWAL FROM THE STUDY: If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled as a DoD beneficiary.

COULD YOUR PARTICIPATION END EARLY? The researcher may withdraw you from the study prior to the study's end and/or the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the researchers and study staff.

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- The researcher decides that continuing your participation is not in your best interests.
- The study is cancelled.
- Unanticipated circumstances.

If you lose your status as a military health care beneficiary, you can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation.

BENEFITS: The possible benefits of your participating in this study is improvement in pain and satisfaction. However, there is no guarantee or promise that you will receive any personal benefit from this study. We hope the information learned from this study may help future patients.

COSTS: Will taking part in this study cost anything? The investigators have designed this study so that there is no cost to you to participate in this study, other than what it will cost you to travel to your standard of care appointments.

The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care is governed by Federal laws and regulations.

PAYMENT (COMPENSATION): You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS: Choosing not to participate and receive standard of care treatment for low back pain is the only alternative to participating in this study.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION: Records of your participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, *Privacy Act Statement- Military Health Records*, contains the Privacy Act Statement for the records. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. You will not be personally identified; all information will be presented as anonymous data. Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. Your medical record will be annotated to reflect you are participating in a research study that involves a treatment intervention that is for research purposes only. All information about you collected on this study will be kept in an electronic database, which will be double password-protected, firewall-protected and access-restricted to people involved in this study. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent. The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you

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inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you in contacting the 59 MDW Privacy Office for assistance.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE: If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors. If you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the 99 MDG Human Protection Administrator at (702) 653-3298.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in the study.

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DE-IDENTIFIED RESEARCH DATA: All de-identified research data obtained from this study will be kept at the Mike O'Callaghan Military Medical Center, Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of the 99MDG will have access to this database without permission of the "Mike O'Callaghan Military Medical Center General Research Data Repository (FWH20180064H"), Manager Dr. Paul Crawford and the Wilford Hall Ambulatory Surgery Center (WHASC) 59th MDW Institutional Review Board (IRB).

The Investigators are asking for permission to store your de-identified research data in the above database repository for future use in research studies. The specifics of these research studies are unknown at this time. Your stored de-identified research data will be information such as gender, age, medical history, and laboratory tests. This data is considered de-identified information and cannot be traced back to you when added to a database. The Principal Investigator and Database Repository Manager will take every precaution possible to safeguard your information to eliminate the possibility of any breach of confidentiality. This is explained above in the section, "Confidentiality".

The Database Repository Manager, Dr. Paul Crawford, is responsible for all de-identified research data stored in the repository. All recipient investigators requesting data from the repository must have approval from the Database Repository Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and the 59th MDW IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information can't be traced back to the donor of the data. Recipient investigators may only receive limited data sets of de-identified information necessary to conduct their research. Additional consent from you in the future will not be required to share de-identified data, since this consent for satisfies this requirement. Generally, you will not be provided with the results of these research studies from the repository. Any results would be of unclear value and unknown clinical meaning, since your de-identified data will be combined with other de-identified data from numerous patients used for the study. You will not be able to request that your de-identified research data be withdrawn from the database repository, since we will have no way of identifying your specific data. If you have any questions, you can contact: Dr. Paul Crawford, MD, c/o Department of Medical Education, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.

Choose one:

☐ NO: I do not authorize the storage of my de-identified research data in this repository.

☐ YES: I authorize the storage of my identifying de-identified research data in this repository.

_____

Patients' Signature

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CONTACT INFORMATION:

****In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.****

Principal Investigator (PI):
The principal investigator and an alternate member of the research staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Maj Lindsey Schmelzer Duty Phone: (702) 653-3619 After-Hours Phone: (702) 349-0452

Associate Investigator: Maj Danny Villalobos Duty Phone: (702) 653-2344 After-Hours Phone: (702) 349-0452

Institutional Review Board (IRB): The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at 210-292-4683. You can contact the IRB by calling the Chairperson of the 59 MDW IRB at 210-916-8251, or by mail to IRB at 59 MDW/STC, 1100 Wilford Hall Loop, Bldg. 4430, JBSA Lackland, Texas 78236. If you have any questions about your rights as a research subject, research-related injuries or any other concerns that cannot be addressed by the PI, you can also contact the 99MDG Human Protections Administrator (702) 653-3298. All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form will be given to you for your records.

_____ _____
VOLUNTEER'S SIGNATURE **DATE**

_____
PRINTED NAME OF VOLUNTEER

_____ _____
STUDY STAFF SIGNATURE **DATE**

_____
PRINTED NAME OF STUDY STAFF

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