Pilot Study: Effect of Battlefield Acupuncture Needle Selection on Symptom Relief and Patient Tolerance in the Treatment of Pain

NCT04464954

13 Nov 2020

FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

99th Medical Group

Title of Protocol:	Pilot Study: Effect of Battlefield Acupuncture Needle Selection on Symptom Relief and Patient Tolerance in the Treatment of Pain
FWH #:	20200117H

KEY INFORMATION ABOUT STUDY PARTICIPATION: You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make a decision. The purpose of this study is to determine the effectiveness of acupuncture in treating pain and to determine which type of acupuncture needle is best tolerated by patients based on their post-treatment experience using acupuncture needles. The needles being studied are the semi-permanent (ASP) acupuncture needles, the intradermal (long) acupuncture needles, and the Pyonex acupuncture needles. The technique being used to place these needles is called Battlefield Acupuncture (BFA). We are recruiting male and female active duty and DoD beneficiaries, aged 18 years or older with complaints of pain. Your participation in this study would consist of one screening visit to review your eligibility for the study. Once you are deemed eligible to participate (after being consented), you will be randomized (like flipping a coin) into 1 of 3 study groups. Group 1 will receive auricular semi-permanent (ASP gold) acupuncture needles, group 2 will receive Intradermal (long) acupuncture needles using J-type No. 1 (.16) x 15mm, group 3 will receive Pyonex Pink 1.5mm (0.2 x 1.5mm) acupuncture needles. Prior to acupuncture treatment, you will be prescribed the anti-inflammatory drug (NSAID) naproxen 220mg by mouth twice a day as needed as standard of care treatment for pain and asked to complete the Defense and Veterans Pain Rating Scale and DVPRS Supplemental Questionnaire (DVPRS). You will then be given treatment according to your study group and asked to complete the DVPRS and DVPRS Supplemental Questionnaire and Needle Tolerance Questionnaires either on-line (via Survey Monkey or Google Docs), in person or via telephone within 10-15 minutes post treatment, 24 hours post treatment, and 7 days post treatment.

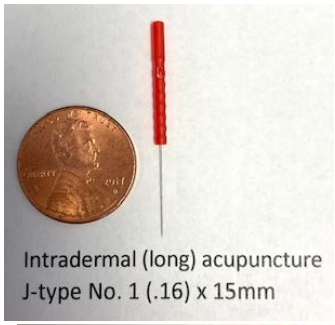
Defense and Veterans Pain Rating Scale and DVPRS Supplemental Questionnaire (DVPRS) is a tool used to assess overall pain and its effect on your life.

Needle Tolerance Questionnaire is a tool used to assess your experience and satisfaction with the acupuncture you received as part of this research study.

The type of acupuncture being used in this study is routinely done as part of an adjunct therapy with other standard of care treatments in our Family Medicine Residency and Acupuncture Clinics. However, for this study, the acupuncture is deemed a research-related intervention and is being used with the standard of care “naproxen 220mg”. Acupuncture is not being offered as a standalone treatment intervention on this study.

Acupuncture is a method where doctors place small needles into certain points in your body to stimulate a reduction in pain. Acupuncture is a form of alternative medicine in which certain points on the body, when stimulated, are believed to correspond with specific areas of the body. The purpose of acupuncture is to balance the flow of the body’s energy, which is supposed to release chemicals to targeted areas of the body to achieve results (for example, these points are used to reduce

pain associated with pain). One acupuncture technique being used in this research study is call Battlefield Acupuncture, which utilizes up to 10 acupuncture needles (5 in each ear) using either the semi-permanent (ASP gold) acupuncture needles, Intradermal (long) acupuncture needles using J-type No. 1 (.16) x 15mm, or Pyonex Pink 1.5mm (0.2 x 1.5mm) acupuncture needles. The ASP semi-permanent Battlefield Acupuncture needles are semi-permanent needles that will remain in your ears for 2-8 days and will be allowed to fall out on their own. Intradermal (long) needles will remain in your ears for 15-30 minutes and will be removed by a member of the study staff. Pyonex needles will remain in your ears for 2-21 days and allowed to fall out on their own.



Risks and side effects related to your participation in this study include:

ACUPUNCTURE:
LIKELY: *Likely and not serious:*

- Pain
- Bleeding
- Flare of signs and symptoms

LESS LIKELY: *Less Likely and not serious:*

- Infection

As a FEMALE OF CHILDBEARING POTENTIAL wishing to volunteer for this project, you must understand that your participation might be harmful to an unborn child if you are pregnant, or become pregnant. Therefore, you may not be pregnant and take part in this study. You must agree to take precautions to prevent pregnancy during the course of this study due to the possible harm the procedure may cause your unborn child. The only completely reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, intrauterine device (IUD), or sperm-killing products are not totally effective in preventing pregnancy.

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If you become pregnant or feel you might be pregnant, contact your provider and the study investigator listed in the voluntary participation section.

There is also a risk of accidental breach of confidentiality.

The possible benefit of your participation in this study is that you may experience an improvement in pain. 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. You will be prescribed the anti-inflammatory drug (NSAID) naproxen 220mg by mouth twice a day as needed as standard of care treatment for pain regardless of the treatment group that you are randomized into. You can still receive other standard of care treatments for your pain without participating in this study. The only reason the acupuncture intervention is considered 'research" is because we are randomizing you into groups.

INFORMATION ABOUT THIS CONSENT FORM: You may be eligible to take part in a research 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:
Paul Crawford, MD	CIV	USAF	Family Medicine Residency, 99MDG

PURPOSE OF THIS STUDY (Why is this study being done?)**:** The purpose of this study is to determine which acupuncture needle patients tolerate better and to identify patient experiences using each acupuncture needle in male and female patients aged 18 years or older with pain.

This study will enroll approximately 39 subjects at 99MDG (Nellis AFB).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, a publicly available Federal website, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. Additionally, an IRB-approved copy of the clinical trial template consent form will be posted with no subject information included on the form. You can search this website at any time.

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If you decide to take part in this research study, you will be asked to sign this consent form.

SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY: Some exams, tests, and/or procedures (see below under Screening Visit) may be done after you sign this consent to participate in this study. This screening is done to find out if you can continue in the study after consenting (screening procedures). We may be able to use the results of some standard of care exams, tests, and/or procedures you completed before enrolling in this study to avoid any additional screening tests. You will be told which results we will be able to obtain from your medical records and which procedures and/or tests will not require repeating. All of the research-related procedures for the screening visit will add approximately 20 minutes to the length of your routine care visit. If you are not allowed to continue in the study, the researcher will discuss the reasons with you. Any procedure described below as "standard of care" would be done even if you do not take part in this research study.

Screening Visit:

- Obtain your signed Informed Consent Document and HIPAA Authorization.
- Review your past medical history.
- We will record your date of birth, age, gender, contact information, DoD ID number, name of standard of care medications (over-the-counter and prescription).
- Females of childbearing potential participating in this study will be reminded that they only reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, intrauterine device (IUD), or sperm-killing products are not totally effective in preventing pregnancy. They will be asked to alert study staff if they become pregnant or feel that they might be pregnant.

Study Procedures: As a participant, you will undergo the following procedures.

Assignment to Research-Related Study Groups: When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to 1 of 3 study groups:

- Group 1: Auricular semi-permanent (ASP gold) needles
  Group 2: Intradermal (long) needles using J-type No. 1 (.16) x 15mm
- Group 3: Pyonex Pink 1.5mm (0.2 x 1.5mm)

Treatment Visit (Day 0) (may be same day as screening visit):

- You will be asked to complete the Defense and Veterans Pain Rating Scale and DVPRS Supplemental Questionnaire (DVPRS) before treatment.
- You will be prescribed the anti-inflammatory drug (NSAID) naproxen 220mg by mouth twice a day as needed as standard of care treatment for pain.
- Acupuncture will be performed.

Post-Treatment Visit (10-15 minutes Post Treatment) (in-person):

- You will be asked to complete the DVPRS and DVPRS Supplemental Questionnaire.
- You will be asked to compete the Needle Tolerance Questionnaire.

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Contact 1 (24 hours Post Treatment) (in-person, via telephone, or on-line via Survey Monkey or Google Docs):

- You will be asked to complete the DVPRS and DVPRS Supplemental Questionnaire.
- You will be asked to compete the Needle Tolerance Questionnaire.

Contact 2 (7 days Post Treatment) (in-person, via telephone, or on-line via Survey Monkey or Google Docs):

- You will be asked to complete the DVPRS and DVPRS Supplemental Questionnaire.
- You will be asked to compete the Needle Tolerance Questionnaire.

RISKS OR DISCOMFORTS: There are risks to taking part in this research study. One risk is that you may have side effects while on the study. Some side effects are more likely to occur than others. You may experience a certain side effect many times, a few times, or only once or twice, if at all. 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 the study. The following section will describe the risks related to the research intervention that is part of this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in this study.

ACUPUNCTURE:

LIKELY: *Likely and not serious:*

- Pain
- Bleeding
- Flare of signs and symptoms

LESS LIKELY: *Less Likely and not serious:*

- Infection

As a FEMALE OF CHILDBEARING POTENTIAL wishing to volunteer for this project, you must understand that your participation might be harmful to an unborn child if you are pregnant, or become pregnant. Therefore, you may not be pregnant and take part in this study. You must agree to take precautions to prevent pregnancy during the course of this study due to the possible harm the procedure may cause your unborn child. The only completely reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, intrauterine device (IUD), or sperm-killing products are not totally effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant, contact your provider and the study investigator listed in the voluntary participation section.

There is also a risk of accidental breach of confidentiality.

WITHDRAWAL FROM THE STUDY: If you first agree to participate and then change your mind, you are free to withdraw consent and discontinue 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. There are no risks from withdrawing. If you decide to withdraw from the study early, please discuss your decision with the study staff. The

researcher may withdraw you from the study prior to the study's end, without your consent, for one or more of the following reasons: Failure to follow the instructions of the researchers and study staff, the researcher decides that continuing your participation is not in your best interest, the study is cancelled, other administrative reasons, unanticipated circumstances, or you become Pregnant. If you lose your status as a military health care beneficiary, you can no longer be included in the study.

BENEFITS: The possible benefit of your participating in this study is that you may experience an improvement in pain, however, this is not a guarantee.

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 the research appointments, beyond any scheduled standard of care medical 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: You can still receive conservative management or acupuncture for your pain without participating in this study. Conservative management for pain, consists of a wide range of treatment options and combinations. A partial list would include physical therapy, injections (including dexprolotherapy, corticosteroids, PRP), oral medications, osteopathic manipulation, massage, heat, ice, and rest. The only reason this is considered "research" for this study is because we are randomizing you into research groups. You also have the option not to participate in the 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 Air Force, the DoD, other government agencies that oversee human research, the 59 MDW Institutional Review Board, and Human Protection Administrators at 99MDG.

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-

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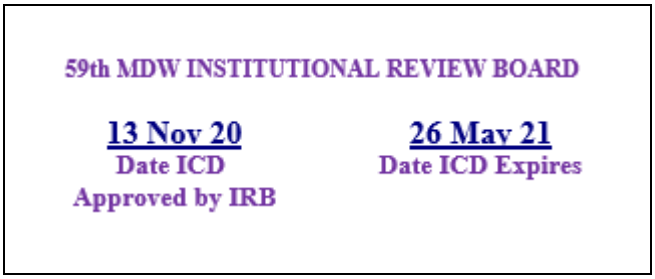

protected, firewall-protected and access-restricted to people involved in this study. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will 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 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 also contact the 99MDG Human Protection Administrator at 99MDG 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 this study.

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PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA: All de-identified research data 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 "Nellis Acupuncture Research Data Repository (FWH20140048H)", Manager Dr. Paul Crawford and the Wilford Hall Ambulatory Surgery Center (WHASC) 59th MDW Institutional Review Board (IRB).

The Investigators are asking for your permission to store your de-identified research data in the 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 is the data we obtain from you during your participation in this research study. This data is considered non-identifying information and cannot be traced back to you as a donor 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 cannot 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. Generally, you will not be provided with the results of these research studies using your de-identified data from the repository. Additional consent from you in the future will not be required to share de-identified data, since this consent form satisfies this requirement. 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 to identify whom the data belongs to. If you have any questions, you can contact the Database Repository Manager at Dr. Paul Crawford or mailing your request to the following address: 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 de-identified research data in this repository.

_____

Signature of Study Participant

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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.

Contact	Phone	Off-Duty Phone
Dr. Paul Crawford	(702) 653-3298	(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 call the Research Hotline at 210-292-5146 or 59 MDW Authorized Institutional Official (AIO) at 210-292-3355.

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**

_____

VOLUNTEER'S PRINTED NAME

_____ _____

ADVISING STUDY STAFF'S SIGNATURE **DATE**

_____

PRINTED NAME OF ADVISING STUDY STAFF

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