An Exploratory Prospective Trial of Rescue Acupuncture for the Treatment of Acute Migraine.

NCT02764996

June 29, 2016

Volunteer Name: _____

WILFORD HALL AMBULATORY SURGICAL CENTER
INFORMED CONSENT DOCUMENT

An Exploratory Prospective Trial of Rescue Acupuncture for the Treatment of Acute Migraine..
FWH20150084H

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 in more than one place in this document.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, 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 procedures of the study and what the study is about, including the risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION:
Taking part in this study is completely voluntary. You should not feel coerced or intimidated into participating in this project. You do not have to participate if you don't want to participate in the study. You do not have to participate in this study in order to get standard medical treatment. 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. If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

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 Sarah Bobnick, D.O. Capt, Family Medicine Residency Program Director, Mike O'Callaghan Federal Medical Center.

PURPOSE OF THIS STUDY (Why is this study being done?)**:**
You are being asked to consider participation in this study because you have been previously prescribed rescue medication to treat your acute migraine episodes. The purpose of this study is to see if standard of care acupuncture in addition to your standard of care rescue medication helps reduce pain and the amount of rescue medications that you use.

This study will enroll approximately 60 subjects.

This type of Acupuncture for the treatment of migraine headaches is routinely done in the Family Medicine and acupuncture clinics both in combination with rescue medications and as a stand-alone therapy.

Acupuncture is a method where doctors place small needles (see figure 8 below) into certain points in your body (see figures 1-7) 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 migraine headache pain).

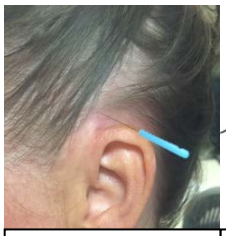

Figure 1: N Point

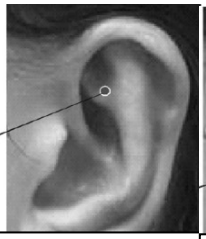

Figure 2: Shen Men

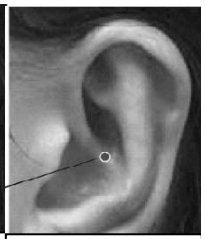

Figure 3: Point Zero

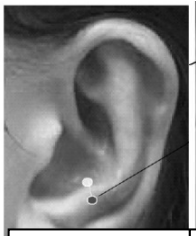

Figure 4: Thalamus

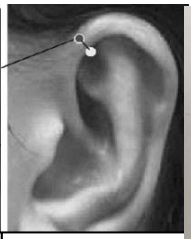

Figure 5: Omega 2

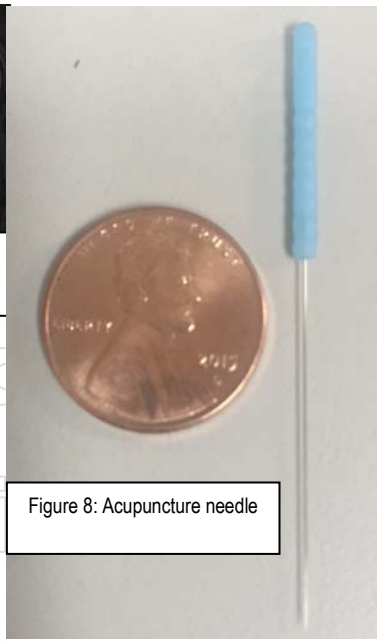

Figure 8: Acupuncture needle

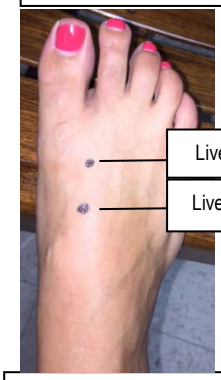

Figure 6: Liver 2 & Liver 3

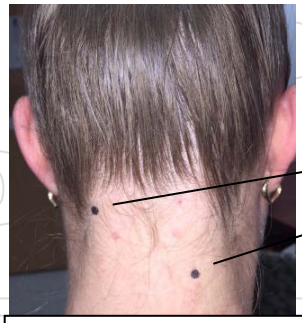

Figure 7: Gallbladder 20 & Bladder 10

Acupuncture uses a simple, systematic approach to placing the needles that can be learned by non-acupuncture trained providers in a short amount of time. Landmarks on the body are easily identified and no equipment, other than the needles, is required. The needles being used stay in place for 20-30 minutes and are then removed prior to the end of your appointment.

The acupuncture needles used in this study are exempt from Food & Drug Administration (FDA) clearance or approval but the FDA has published safeguards for their use. This study will follow all FDA requirements for the safe use of these devices.

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 be asked to make up to 7 visits with Sarah Bobnick, D.O. Capt, the Principal Investigator (PI) or study staff.

Screening Procedures– a history will be taken after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). This screening visit will add approximately 20 minutes to the length of a routine care visit. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Screening Visit:

- Obtain your signed Informed Consent Document and HIPAA Authorization. (research only)
- Review your past medical history. (research only)
- We will record your date of birth, age, gender, race, ethnicity, last 4 of social security number, the name and dosages of the over-the-counter and prescription headache medicines you take, current email address (to assist with scheduling), height, weight, history of traumatic brain injury, concussion, or any mild to severe head trauma, medication use, and history of any prior acupuncture. (research only)
- We will ask what your expectations are regarding acupuncture's effectiveness for migraine. (research only)
- You will be instructed not to take your over-the-counter and prescription headache medications until after your visit with the research staff. (Standard care only)
- You will be instructed to bring your over-the-counter and prescription headache medications with you to each visit if your symptoms do not resolve from the acupuncture treatment. (research only)
- You will be instructed to contact the research staff, as soon as possible, after onset of migraine symptoms to schedule an emergent visit with the research staff. . (research only)
    - If you have a rapid onset migraine and are unable to drive or find someone to drive you, then we will ask you not to come in for a visit during that migraine episode for your safety.
- You will be given a contact card with the names and phone numbers of the research staff to contact when you have a migraine episode.

Study Procedures-as a participant, you will undergo the following study-related procedures:

Migraine Episode (you will acupuncture treatment for up to 6 different migraine episodes over the course of 3 months):

- You will be asked to rank the severity of your headache pain (0=no headache, 1=mild, 2=moderate, 3=severe) (Standard care only)
- We will record the name and dosages of the over-the-counter and prescription headache medicines you took in the past 7 days. (research only)
  Acupuncture will be administered and you will sit, with the needles in place, for 20-30 minutes. (Standard care only)*If after 20-30 minutes you have not had relief from your headache, you will be instructed to take your headache medication. (research only)
- You will again be asked to rank the severity of your headache pain (0=no headache, 1=mild, 2=moderate, 3=severe) (research only)
- You will leave and be informed of the following telephone follow ups:
- 2 Hours post acupuncture (research only):
    - You will again be asked to rank the severity of your headache pain (0=no headache, 1=mild, 2=moderate, 3=severe)
- 4 Hours post acupuncture (research only)
    - You will again be asked to rank the severity of your headache pain (0=no headache, 1=mild, 2=moderate, 3=severe)
- 24 Hours post acupuncture (research only):
    - You will again be asked to rank the severity of your headache pain (0=no headache, 1=mild, 2=moderate, 3=severe)
    - Would you use acupuncture for future pain management? (Yes or no)

- Would you prefer acupuncture or your rescue meds (both over-the-counter and prescription) for future episodes?
- Record type and amount of rescue medications (over-the-counter and prescription) used since acupuncture.

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

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. You may experience a certain side effect many times, a few times, or only once or twice, if at all. Some side effects are more likely than others to occur.

Research-related side effects from this study will usually go away soon after the acupuncture needles are removed. 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 acupuncture that is part of this research study.

LIKELY: *Likely and not serious:*
- Pain
- Bleeding

LESS LIKELY: *Less Likely and not serious:*
- Infection

For more information about risks and side effects, ask one of the researchers or study staff.

Are there risks if you also participate in other research studies? Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

There may also be unforeseen risks associated with this or any research study.

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.

ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY?
There are no risks to you if you withdraw from this study. If you decide to withdraw from this study early, please discuss your decision with the principal investigator.

ADDITIONAL CIRCUMSTANCES OF WITHDRAWAL:
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 interests.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.
- You become Pregnant
- You begin taking anticoagulants

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 staffs know as soon as you become aware of your situation.

BENEFITS:
The investigators have designed this study to learn if the addition of acupuncture to your standard of care helps with reducing pain and rescue medication use but there is no guarantee or promise that you will receive any benefit from this study other than knowing that the information 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 the research appointments.

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

ALTERNATIVES TO PARTICIPATION:
Acupuncture for migraine is done in the Family Medicine Residency as part of standard of care. You may choose to get this type of acupuncture without 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 medical science. 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 Department of Defense (DoD), Mike O'Callaghan Federal Medical Center representatives, or other government agencies that oversee human research, the 59 MDW Institutional Review Board.

Copies of this consent will be placed in your research record. 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. 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. 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.

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:

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors.

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and 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 Wilford Hall Director, Clinical Research Division, (210) 292-7069 or Mike O'Callaghan Federal Medical Center, Nellis Air Force Base, Nevada Privacy Officer at (702) 653-2721.

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.

BLOOD, TISSUE & BIOLOGICAL SAMPLES:

No blood or tissue samples will be taken as part of this study.

PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA:

All PHI and PII data that will be used in the database repository will be kept at the Mike O'Callaghan Federal Medical Center (MOFMC), Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of MOFMC will have access to this database without permission of the "Nellis Acupuncture Research Data Repository (FWH20140048H)", Manager Lt Col Paul Crawford and the Wilford Hall Ambulatory Surgery Center (WHASC) Institutional Review Board (IRB).

For Protocol Office Use Only:
FWH20150084H, Bobnick, ICD, PR 2016

Version: 0514

The Investigators are asking for your permission to store your PHI and PII in the database repository for future use in research studies. The specifics of these research studies are unknown at this time, but these studies will frequently be in the area of acupuncture. Your stored PHI and PII will be information such as gender, birth date, age, height/weight, medical history, laboratory tests, blood pressure, waist circumference measurements and surgical procedures and post-surgery outcomes. This data is considered both identifying and non-identifying information and may be traced back to you as a donor when added to a database. The Principle 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, Lt Col Paul Crawford, is responsible for all PHI and PII 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 WHASC 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.

Generally, you will not be provided with the results of these research studies using your de-identified data 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 may request that your PHI and PII data be withdrawn from the database repository at any time, if you decide you no longer want to participate. This request may be accomplished by calling the Database Repository Manager at Lt Col Paul Crawford or mailing your request to the following address: LtCol Paul Crawford, MD, c/o Family Medicine Residency, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.

_____NO: I do not authorize the storage of my PHI and PII data for future use in research studies.

_____YES: I authorize the storage of my PHI and PII data for future use in research studies.

_____
Signature of Study Participant

CONTACT INFORMATION:

Principal Investigator (PI): The principal investigator or a member of the Family Medicine Residency staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Sarah Bobnick, D.O. Capt Phone: (702) 653-3298

Institutional Review Board (IRB): 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 contact the 59th ST/SGVUS, 2200 Bergquist Dr, Lackland Air Force Base, Texas 78236.

In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the

59 MDW IRB, at (210) 916-8251. Or mail to: 59th Medical Wing/CMO, 2200 Bergquist Drive, Lackland Air Force Base, Texas 78236.
Your consent to participate in this study is given on a voluntary basis. 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 has been given to you.

_____ _____
VOLUNTEER'S SIGNATURE **DATE**

_____
VOLUNTEER'S PRINTED NAME

_____
VOLUNTEER'S ADDRESS (street, city, state, zip)

_____ _____ (702) 653-3298
ADVISING INVESTIGATOR'S SIGNATURE **DATE** **PHONE#**

_____
PRINTED NAME OF ADVISING INVESTIGATOR

_____ _____
WITNESS' SIGNATURE **DATE**
(Must witness ALL signatures)

_____
PRINTED NAME OF WITNESS

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