IRBNet Number: 381600-19
PI: Dr. Anthony Plunkett
Protocol Title: **A randomized, single-blind, prospective trial of auricular acupuncture for the reduction of post-operative tonsillectomy pain in adults.**
Initial Date Submitted: 6/13/2013
Revision Date: 7/17/17

Application and Request for Approval of Study Proposal

1.0 PROTOCOL TITLE: A randomized, single-blind, prospective trial of auricular acupuncture for the reduction of post-operative tonsillectomy pain in adults.

2.0 PRINCIPAL INVESTIGATOR:

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2.1 ASSOCIATE INVESTIGATORS:

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2.2 COLLABORATOR:

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2.3 ROLES AND RESPONSIBILITIES: The Principal Investigator (PI) will be involved in patient recruitment, patient consent, data collection and input, design and oversight of experimental methodology, acupuncture application, any subject follow up if needed, literature review and manuscript writing and continued regulatory communication. Anesthesiologist AIs will be involved in patient recruitment and consent, acupuncture and possibly regulatory communication, data collection, subject follow up if needed, input and coverage of PI in any absences. Robin Howard, MA will doing the final analysis.

3.0 RESPONSIBILITIES OF THE PRINCIPAL/ASSOCIATE INVESTIGATOR IN HUMAN SUBJECTS RESEARCH:

The principal investigator is the individual who is primarily responsible for the actual execution of the clinical investigation. He/she is responsible for the conduct of the study, obtaining subjects' consent, providing necessary reports, and maintaining study documents. The Associate Investigator will assist the Principal Investigator with the responsibilities stated below.

As the Principal Investigator or Associate Investigator:

A. I will not enroll a subject into a study until the study has been approved by the appropriate authority and, when appropriate, the subject's primary care provider has granted approval for him/her to enter a study.

B. By signing this protocol, I warrant that any use of Protected Health Information (PHI) for reviews preparatory to research met the following requirements:

i. The review of PHI was done solely to prepare a research protocol, or for similar purposes preparatory to research;
ii. No PHI was taken outside the Military Health Care System or disclosed to persons not having a need for this information; and
iii. This review of PHI was necessary for research purposes

C. I am responsible for assuring that the prospective volunteer is not participating as a subject in other research that will significantly increase the research risks to the subject.

D. I am responsible for assuring the quality of each subject's consent in accordance with current federal regulations. This will include ensuring that any "designee" that obtains consent on my behalf is completely conversant with the protocol and is qualified to perform this responsibility.

E. I will obtain the WAMC IRB approval for advertisements used to recruit research subjects.

F. I will not accept any outside personal remuneration for implementation of a study.

G. I will take all necessary precautions to ensure that the study does not generate hazardous chemical waste.

H. I will obtain the proper WAMC clearance prior to all presentations, abstracts, and publications. The following require WAMC approval:

i. Reports involving WAMC subjects and/or patients.
ii. Reports that cite WAMC in the title or byline.
iii. Reports of WAMC approved clinical investigation or research.
iv. Reports of research performed at WAMC.
v. Reports of research conducted by WAMC assigned personnel.

I. I will obtain proper Office of the Surgeon General (OTSG) publication clearance prior to all presentations, abstracts, and publications that involve:

i. Traumatic brain injury
ii. Post-traumatic stress disorder
iii. Poly-pharmacy
iv. Pain

(Contact Ms. Zabel at ethel.m.zabel.civ@mail.mil for assistance.)

J. I must submit to the Clinical Investigation Service (CIS):

i. Any source of outside funding.
ii. An annual Continuing Review Report (CR), due in the anniversary month of the protocol's initial approval or due in the month as determined by the IRB for continuing review and approval.
iii. Reports of adverse effects occurring in subjects as a result of study participation or of any protocol deviations and submit these reports to Research Monitor if there is one for the study.
iv. An Addendum, prior to any changes made to the study or a change in the funding status.
v. Listing of presentations, abstracts, and publications arising from the study for inclusion in the CR.

K. I will maintain a Study File that must be kept for six years following completion of the study if no IND/IDE used (32 CFR 219.115(b). If IND medication or IDE appliances are used, the file must be kept for 2 years after FDA approval and can then be destroyed; or if no application is filed or approved, until 2 years after the study is discontinued and FDA notified (21CFR 312.62(c). The records should be kept in the Department/Service where the research took place (AR 40-38). If I am scheduled to PCS or ETS, I will notify the Clinical Investigation Service as soon as I am aware but at least 3 months prior to departure. Records will be given to a new WAMC PI or the Department/Service Chief.

L. I will be familiar with all applicable regulations governing research, and will adhere to all of the requirements outlined in the WAMC's DOD Assurance and Federal-Wide Assurance granted by the Office for Human Research Protections, Department of Health and Human Services.

M. Research Monitor

If it is determined that a Research Monitor is assigned to the research study, I agree to provide the name, human subject protection training and curriculum vitae of the research monitor. I acknowledge that this individual will be qualified (e.g., Medical Doctor, Nurse Practitioner, etc). The research monitor will review all unanticipated problems involving risk to the subjects or others, serious adverse events and all subject deaths associated with the protocol and provide an unbiased written report of the event. At a minimum, the research monitor will comment on the outcomes of the event or problem, and in the case of a serious adverse event or death, comment on the relationship to participation in the study. The research monitor will also indicate whether he/she concurs with the details of the report provided by the study investigator. Reports for events determined by either the investigator or research monitor to be possibly or definitely

related to participation and reports of events resulting in death will be promptly forward to the WAMC IRB.

N. Active Duty Military Personnel as Study Subjects

Special consideration will be given to the recruitment process for military personnel. The Chain of Command will not be involved in the recruitment of military personnel and will not encourage or order soldiers to participate in research study. An ombudsman will be used when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary. Restrictions on compensation for active duty military members will be adhered to as applicable.

O. Title 10 United States Code 980

I acknowledge the requirements of Title 10 United States Code 980: "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless-(1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

If an individual cannot give his or her own consent (e.g., incapacitated individuals, incompetents, minors) to participate in the research study, consent of the individual's legally authorized representative will be obtained prior to the individual's participation in the research. Moreover, such subjects will not be enrolled in DoD sponsored research unless the research is intended to benefit each subject enrolled in the study.

4.0 LOCATION OF STUDY:

Womack Army Medical Center

5.0 DURATION OF STUDY:

Expected Start Date for Data Collection: July 2013

Expected Completion Date for Data Collection: July 2017

Expected Completion Date for Study (to include data analysis): January 2018

6.0 BACKGROUND AND LITERATURE REVIEW:

Date of Search: 01 April 2013
Period Searched: 1970s-present
Sources Searched: Pubmed; OVID
Keywords Searched: acupuncture; tonsillectomy; auricular acupuncture; battlefield acupuncture

Tonsillectomy is one of the most commonly performed surgical procedures in the United States. While the procedure is more commonly performed in pediatric patients, greater than 130,000 were performed for patients older than 15 years in 1996.[1] Indications for tonsillectomy in adults primarily include recurrent tonsillitis, soft tissue obstruction, and neoplasm.[2] Several variations of surgical technique are available, each having a different impact on post-surgical bleeding and pain.[3, 4, 5] These most commonly include cold dissection, electrosurgery, harmonic scalpel, laser dissection, guillotine tonsillectomy, argon plasma coagulation, and coblation. Each of these methods possesses its advantages and disadvantages, and the decision on which to use typically rests on the surgeon's own preference and training.[6] However, all of these techniques result in significant post-operative pain, with this found to be worse in adults.[7] Patients experience a high level of pain usually for the first four days after surgery, and pain can persist for up to ten days. Opioids are the most commonly prescribed analgesics for post-operative pain in adults.[8]

Opioids, steroids, and non-steroidal anti-inflammatory agents have all been utilized in the attempt to minimize pain.[9,10,11] Although shown to be effective in controlling post-operative pain, the use of narcotics comes with unpleasant side effects such as nausea, vomiting, and constipation.[12] As dehydration is a common complication after a tonsillectomy due to limited swallowing capability, the side effects of narcotics can further exacerbate this problem.[13] Other commonly used treatments for pain include non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen. Both have been found to be effective in controlling post-operative pain, but should be used with caution. Due to their antiplatelet effect, NSAIDs in particular can be harmful after tonsillectomy, as bleeding is a common morbidity with this surgery. Acetaminophen has little impact on clotting; however, long-term usage or over dosage can result in liver failure.[14] Steroids (typically dexamethasone) are used to prevent inflammation, but may also have some analgesic benefit. While no adverse effects have been shown, efficacy studies have produced mixed results, with some reporting an improvement in pain post-operatively and others reporting no effect observed.[15,16,17] Another alternative treatment for post-operative pain is a local anesthetic administered either by infiltration or applied topically. While moderately improving pain after surgery, this method was not found to reduce the use of supplemental analgesia.[18] As demonstrated, pharmacotherapy has its benefits and its risks. As such, alternate methods for controlling post-operative pain should be considered.

Acupuncture is an ancient Chinese method of treating pain in which needles are inserted into zones on the body that correspond to certain body parts.[19] Although used in traditional Chinese medicine for centuries, acupuncture as an alternative method of treating pain in the Western world has been a topic of increased clinical studies over the past few decades, as it is relatively low-risk and cost-effective. A literature review of studies dating back to the 1970s indicated that a vast majority of the data pointed to the efficacy of acupuncture in treating neck and back pain, dental pain, musculoskeletal and arthritic pain, as well as chronic pain.[20,21,22,23,24] A more recent meta-analysis demonstrated further mounting evidence of the analgesic effects of acupuncture on a wide variety of pain, including osteoarthritis and migraines.[25] Its potential in post-operative analgesia has also been studied, and acupuncture has been shown to reduce pain as well as decrease the use of opioids after a number of various surgeries.[26] Although a few

studies have given inconclusive results, there is an overwhelming amount of promising data to suggest that acupuncture may play an important role in analgesia.

Many different acupuncture techniques are commonly used for managing pain; specifically, auricular acupuncture has been a long-standing therapeutic modality dating back thousands of years. The use of auricular acupuncture has been applied to many conditions including headache, allergic rhinitis, chronic fatigue, anxiety and pain.[27,28,29,30,31] The hypothesized efficacy of auricular acupuncture comes from the premise that the external ear represents a microsystem of the entire body. The ear serves as a miniature homunculus, whereby specific points on the ear correspond to specific areas of the body.[32] A modified technique, referred to as Battlefield Acupuncture (BA), was developed by Dr. Richard Niemtzow in 2001 and utilizes only five major auricular points (see Figure 1). Dr. Niemtzow collaborated with a neurophysiologist to determine which areas of the brain were activated in patients experiencing pain. They utilized functional MRI to visualize these pain centers and found less activity in these areas after the application of auricular acupuncture. [32] BA is an appealing method of analgesia since it can be easily taught, easily applied, does not require highly specialized equipment or sterile operating conditions, and is inexpensive. Furthermore, its risks are minimal, including irritation or possible infection of the ear. [32] To our knowledge, this is the first single-blinded, prospective, randomized trial evaluating the efficacy of BA in reducing post-operative pain for adult tonsillectomy.

6.1 REFERENCES:

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7.0 PURPOSE: To determine if auricular acupuncture significantly reduces post-operative pain in comparison to the standard of care. Post-operative pain score will be collected by subject self-

report of pain according to the Numerical Rating Scale (NRS) (0= no pain, 10 = worst imaginable pain) up to 10 days post-operation.

7.1 HYPOTHESES/RESEARCH QUESTIONS: We hypothesize that subjects receiving intra-opertive auricular acupuncture during a tonsillectomy will have statistically significantly less post-opertaive pain scores in comparison to subjects receiving standard of care.

7.2 SPECIFIC AIMS/SIGNIFICANCE:
Aims: The specific aim of this study is to compare post-operative pain, as measured by Sum of Pain Intenstity (SPI) from the time of first to waking to 10 days post-opertative using the Numerical Rating Sacle (NRS), between subjects receiving intra-operative auricular acupuncture or standard of care during a tonsillectomy.

Significance: Post-opertive pain in adults after a tonsillectomy is significant, despite surgical technique and medication management. Identification of an intra-opertive intervention that results in significant reduction in post-operative pain would improve patient's quality of life, and may reduce medication usage and improve return-to-duty time.

Secondary aims: We will also compare outpatient pain medication use and resumption of normal diet between subjects receiving intra-operative auricular acupuncture or standard of care during a tonsillectomy.

7.3 DESIGN:

- **Design type: Prospective, randomized control trial**
- **Sample**
  - **Description of the population:** All adults (>18 years) undergoing a tonsillectomy with or without adenoidectomy at WAMC are eligible for participation in the study.
    - **Sample Size: 125 subjects.** A target of 45 subjects per group for a total of 90 subjects, and accounting for a 10% drop out rate. With current diary return low, to ensure complete data for analysis we will continue to recruit and enroll up to 125 subjects.
  - **Power Analysis:** Under the assumption of a linear time by treatment interaction, assuming subject-level randomization, five time-points, power of 80%, a Type I error rate of 5% and no attrition, to detect a 1.6 difference in pain score requires a total sample size of 90 subjects or 45 per treatment arm.
  - **Inclusion Criteria:**
    - All adults (males and females) 18yrs of age or older having a tonsillectomy or tonsillectomy with adenoidectomy.
    - ASA I-III
  - **Exclusion Criteria:**
    - Chronic pain syndromes (pain symptoms lasting greater than three months or taking opioids on a daily basis for > 3 months)
    - ASA IV

- Prior neck or throat surgery
- Allergy to gold

- **Number of Participants:** Up to 125 subjects will be enrolled with a target of 90 subjects (45 per group) that have completed the study. .

- **Explanation of the process from consenting to data collection:**
  - **Randomization:** Before the study begins, a randomized, sequential set of 100 numbered opaque evelopes will be prepared containing assignment to either the acupuncture group or the control group. The randomization list will be generated by a computer program. The evelopes will be stored in the PIs office and opened according to subject number on the day of surgery. To continue enrollment up to 125 another 25 will be randomized using a computer randomization program.

Recruitment:

Recruitment to participants discharge will follow the following steps: .

- Patient sees ENT surgeon for standard of care visit to discuss upcoming (to be scheduled) tonsillectomy with or without adenoidectomy at which time, IRB-approved study flyers will be available to patients in the surgeons' exam rooms.

- The surgeon who is planning a patient's tonsillectomy with or without adenoidectomy gives the clinic Medical Support Assistant (MSA) a surgical scheduling form (STANDARD OF CARE)

- Approximately 30 days prior to surgery, the MSA schedules the patient's tonsillectomy with or without adenoidectomy if a time slot is available; if not, the MSA calls the patient within next 30 days when a slot is available. The MSA also schedules an appointment for the patient to see CRNA and RN (1-3 days pre surgery) (STANDARD OF CARE.) At this time the MSA gives the patient an OPTIONAL RESEARCH PACKET (Appendix G) in which there is the following:

  - Study Flyer (Appendix G)
  - Patient Information sheet (Appendix G)

- The MSA's will go by a specific script on what to say to potential candidates when giving them the OPTIONAL RESEARCH PACKET. (Appendix F) .

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- The PI, AI or any other designated team members will use the S3 list for potential participants that are scheduled for a tonsillectomy with or without adenoidectomy and will call them as previously approved for those that had no address. They will utilize the previously approved script that has been adjusted slightly for their role. (Appendix G1) The PI or AI will go over the consent at the PAU appointment or morning of surgery

giving the potential participants ample time for questions or concerns.

- If a potential participant contacts the study team, a team member will arrange for the participant to review the consent at his or her pre-admission appointment. The study team will ask if the patient would like an emailed copy of the consent document. If yes, the team member will send her/him the consent form by email or postal mail to review. The study team member will not maintain the email or postal address on file.

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- If screening criteria based on inclusion and exclusion criteria are not met the potential participant will be thanked for their time and informed that they do not qualify for the study.

- If the patient meets the screening criteria and verbalizes interest in participating in the study, he or she is notified that s/he can be scheduled to further review and complete the consent paperwork if s/he wishes with study staff when s/he is present for the pre-admission appointment or at another time convenient for the potential participant. Then, at that time, the potential participant will have a chance to review any questions s/he may have about the study and complete the study consent paperwork if s/he wishes to participate. Consenting will take place in advance of the day of the procedure; if possible and if not a team member will meet with potential participant on the day of surgery in holding. Once a subject has consented to be in the study, the individual consenting them will interview them for demographics, medical history, medication history, and allergies (Appendix A). The pain diary will be reviewed at this time as well. If the subject is determined to be eligible for the study, her/his scheduled date of surgery will be confirmed . The PI will keep a list of all subjects and their respective surgery dates in a password protected electronic enrollment log kept in the V drive.

- **Home diary teaching:** At the Pre admit and/or consent appointment, a research team member will review the home pain diary with the subject. They will be asked to record their pain score in 6 hour intervals for 24 hours after hospital discharge and every 24 hours for a total of 10 days after the surgery. Subjects will not be asked to wake up at night to record pain level. Subjects will be asked to return their pain scores by phone,email, or mail (addressed envelope provided). If the subject has not sent their diary by day 15, an attempt at a reminder to the subject via phone call or email (whichever the subject prefers, as collected during enrollment) will be done. .

- **On the day of the surgery:** On the day of surgery, the randomization category will be determined by the PI or AI acupuncturists by opening the corresponding subject number envelope. Prior to surgery, the PI or AI acupuncturists will introduce him or herself to the subject (if not already done so) and confirm enrollment in the study. Anesthesia for the surgical case will then proceed per standard of care.

After the patient has been fully anesthetized, and prior to the start of the tonsillectomy, the study PI or AI acupuncturists will place the acupuncture needles if randomized to the acupuncture group. Initiation of the surgical case will not be delayed for acupuncture needle placement. If the patient is randomized to the control group, no intervention will occur.

The procedure for the auricular acupuncture is standardized based on the Battlefield Acupuncture technique. The ear will be cleaned with alcohol prior to insertion of the needles. Five sterile, single-use, gold needles will be placed in each ear according to the figure below. The needles penetrate about a millimeter (or 4/100ths of an inch) into the skin.

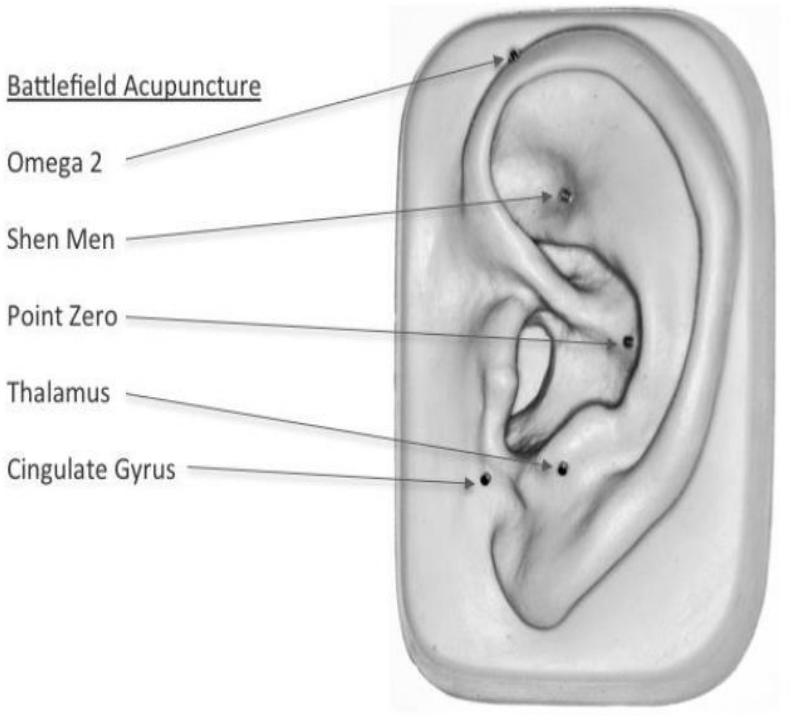

Figure 1. Five points of Battlefield Acupuncture

At the end of the surgical case, prior to fully awakening the patient, the PI or his designeewill remove the acupuncture needles.

Per standard of care, the providing anesthesiologist or PACU nurse will document in Essentris the subject's pain score every 15 minutes for one hour and then hourly until discharge from the PACU. A pain score will also be recorded in

Essentris when prescribed as needed (PRN) pain medications are requested.

Anesthesia and pain medication will be provided per standard of care by the anesthesiologist assigned to the surgical case. All medications given will be documented in Essentris. All discharge instructions by the surgeon and anesthesiologist will be per standard of care.

PACU nurse education will be per standard of care only; the PACU nurse will not be responsible for any study education.

Data will be collected by the PI, AIs, on the day of surgery and recorded on the form found in Appendix B.

Data collection: Data will be collected and entered into three forms (Appendices A-C). All forms will be maintained in a locked file cabinet in the PI's locked office. Data will be collected during the initial subject interview by the individual consenting them (Appendix A), on the day of surgery by the PI (Appendix B), and from the home pain diary. (Appendix C). Data on the day of surgery may also be collected from Essentris or the anesthesia record once the patient has been discharged (as all data needed will be recorded in Essentris or the anesthesia record). Data will be transferred from these forms to an electronic Data base. Each patient will be allocated a study ID number, and thereafter will be referred to by that number in the database. . An Excel spreadsheet with all current data will be where the data is to be entered by a research team member. It will be maintained in the V drive with limited password access. Only research team members will have access.

- Total doses of opioid analgesics in the preoperative, intraoperative and postoperative period will be converted to IV morphine equivalents by the PI or research staff member. They will use John Hopkins Opioid Program's conversion at http://www.hopweb.org/hop/hop.cfm [40]
- **Acupuncture Competence:** The PI cpmpleted the 300 CME Helms Medical Acupuncture Course, the DOD wide approved acupuncture course.

- **Data Collection Instrument:**
  - **Appendix A: Data collection form for demographic and contact information to be collected after initial consent prior to surgery**
  - **Appendix B: Data form for day of surgery data collection**
  - **Appendix C: The home diary to be completed by the subject**

- **Other Appendices**

  - **Appendix D: Flow chart of recruitment to discharge**
  - **Appendix E : Screening inclusion/exclusion**
  - **Appendix F: Script for MSA's (Medical Support Assistants)**

- **Appendix G: Optional Research Packet (flyer/information sheet/envelope)**
- **Appendix H: Data Excel**

- **Variables/Data Points:**

Figure 2. Table of Variables/Data Points

Variable	Data Source
Age	Patient report
Race	Patient report
Gender	Patient report
Height and Weight	Essentris or Ahlta
Pain scores	Patient report and Essentris
Pre op and PACU pain scores	Essentris
Total time in OR	Essentris
Surgical date	Patient report, confirmed in S3
Total OR time	Essentris
Needle retention time	Documented by the PI
Type of Surgery	Essentris
Needle type	Documented by the PI
Intraoperative anesthetic	Essentris
Dexamethasone dose	Essentris
Total Morphine Equivalent	Essentris and John Hopkins Converstion
Daily pain scores	Home diary
Post op Nausea/Vomiting	Essentris notes
Day diet returned to normal	Home diary
Oral pain meds at home	Home diary

7.4 RISKS TO SUBJECTS: Acupuncture is considered a safe technique with minimal risk to the subject. Acupuncture needles only penetrate the skin approximately one millimeter. Despite the minimal penetratuion, needle insertion poses the risk of infection, bleeding and bruising. All acupuncture needles used in this study will be sterile and inserted after alcohol preparation of the ear surface. The needles are made of gold and pose minimal, if any, allergic reaction.

8.0 DATA ANALYSIS: The primary metric for this study is pain score. Pain scores will be collected for 10 days post-operatively, as previous studies have demonstrated a return to baseline by this time. Pain scores will be collected daily during this time period, resulting in repeated measures for each subject. Analysis will be conducted by mixed models to evaluate both (1) difference in pain scores by groups and (2) rate of change in pain score over time.

Age and sex will be considered as potential confounders. Duration of needle insertion may also be evaluated for effect on outcome, if significant variability in length is noted. The type of surgical technique (cold knife coblation versus cautery) may be a potential confounder. Finally, intra-operative anesthesia and dexamethosone dose will be evaluated for potential confounding.

Figure 3. Data Analysis Table

Statistical Test	Independent Variable/ Predictors Variables	Dependent Variable/ Outcome Variables
Mixed model analysis	Study group randomized to (auricular acupuncture or standard of care)	Pain scores on the NRS (from immediately post-operative to 10 days post-operative)
Student's ttest	Study group randomized to (auricular acupuncture or standard of care)	Day full diet resumed
Student's ttest	Study group randomized to (auricular acupuncture or standard of care)	Total morphine equivalent of home pain meds

9.0 MILITARY RELEVANCE: The use of Battlefield Acupuncture is increasing in all services in the military as a treatment option for pain. The DOD as a whole is implementing and employing BA as taught by Richard Niemtzow to as many medical treatment locations as possible. The military is using it to treat pain and PTSD, and acupuncturists are being hired at the major military medical centers. Several grants have been offered to physicians to attend medical acupuncture courses. Therefore, Battlefield Acupunture techniques will become increasing more common for military physicians. The efficacy of Battlefield Acupuncture for post-operative pain is inconclusive (or untested?). This study may provide the intial work for future incorportion of Battlefield Acupuncture in the operating room, further expanding the role of this technique in the military.

Additionally, faster post-operative recovery (as measured by pain) may benefit the military by decreased healthcare burden and earlier return to duty.

10.0 MEDICAL APPLICATION:

Over the last decade, the concept of multi-modal analgesia has been utilized in the treatment of acute post-operative pain.[33, 34] The American Society of Anesthesiologists published a practice guideline stating: "Whenever possible, anesthesiologists should use multimodal pain management therapy. Central regional blockade with local anesthetics should be considered. Unless contraindicated, patients should receive an around-the-clock regimen of COXIBs (Cox-2 Inhibitors), NSAIDs (Non-Steroid Anti-inflammatory Drugs), or acetaminophen.[35]" The treatment of both acute and chronic pain has received national attention.[36] Several media outlets have reported on the complex problem of adequately treating pain, while trying to minimize or eliminate the misuse potential of narcotic analgesics.[37-39] Furthermore, in an environment where downsizing and costs savings are required, the potential to save money on medical management and reduced adverse side effect related problems will become a major part of military healthcare in the coming years. In 2009, Abbott Northwestern Hospital in Minneapolis conducted a retrospective observational study of the pain management effect of nontoxic, nonpharmacological integrative approaches among 1,839 in-patients to include acupuncture. Two thirds of subjects, mainly post-surgical, had never previously received integrative services. The immediate effect on self-reported pain scores was an average reduction of approximately 55 percent, without increased risk of adverse effects. [41]

11.0 BUDGET:

Will any outside organization provide funding or other resources?

☒ **Yes**
☐ **No**

The funding for this study has ended. The PI chooses to continue enrollment for a larger pool for analysis.

12.0 HIPAA AUTHORIZATION:

i. Are you intending to collect subject's Protected Health Information (PHI) and any of the following 18 personal identifiers?

☐ No – HIPAA does not apply – go to question #**iv**
☒ Yes – please check which ones:

- ☒ 1. Names
- ☐ 2. Street address, city, county, 5-digit zip code
- ☒ 3. Months and dates (years are OK) and ages >89 (unless all persons over 89 years are aggregated into a single category)
- ☒ 4. Telephone numbers
- ☐ 5. Fax numbers
- ☒ 6. E-mail addresses
- ☒ 7. Social security number
- ☐ 8. Medical record number

- ☐ 9. Health plan beneficiary number
- ☐ 10. Account number
- ☐ 11. Certificate/license number
- ☐ 12. Vehicle identification number (VIN) and/or license plate number
- ☐ 13. Device identifiers and serial numbers
- ☐ 14. URLs (Uniform Resource Locators)
- ☐ 15. Internet protocol address number
- ☐ 16. Biometric identifiers, such as finger and voice prints
- ☐ 17. Full face photographic images or any comparable images
- ☐ 18. Any other unique identifying number, characteristic, or code such as patient initials

ii. Can you limit your collection of personal identifiers to just #2, 3 or 18 above?
☐ Yes – then your dataset may qualify as a Limited Data Set – please contact wamcirbadmin@amedd.army.mil for further instructions before completing HIPAA authorizations or waivers thereof. Then go to question #**iv**.
☒ No – Go to question #**iii.**

iii. Is obtaining patient Authorization "impracticable"?
☐ Yes – Authorization may qualify to be waived by the IRB. Please contact wamcirbadmin@amedd.army.mil for instructions.
☒ No – Research subjects will need to sign a HIPAA Authorization.

iv. What precautions will you take to protect the confidentiality of research source documents (Case Report Forms, questionnaires, etc.), the research data file, and the master code (if any)?

- All the enrolled subjects will be assigned a study identification number which will not be linked to any Identifiable Protected Health Information (PHI). There will be a master list linking the subject, including the subject's social security number, with the study ID which is kept in a password protected file on the V: drive . The subject's Social Security or other PHI will not be included in the study database. The master list will be destroyed after the study has been completed and all the data has been analyzed.

- Deidentified database without links to subject identifiers in an Excel spreadsheet will be stored on the WAMC V: drive. The deidentified data will only be shared among the PI, AI and collaborators of this study.

- The pain diary along with other case report forms will only be marked with the study ID and will be kept in a locked file cabinet in the research coordinator's locked office.

v. When will you destroy the research source documents, data file, and the master code?
Research data to include ICF/HIPAA authorization will be kept for 6 years after completion of study and then destroyed in accordance with current data destruction policy.

vi. Will research data including identifiable Protected Health Information be sent outside of

WAMC?
☐ Yes
☒ No

vii. Linkage of extracted data to other databases: N/A

12.1 BENEFITS: Identification of a minimal risk intra-operative technique that minimizes post-operative pain benefits the healthcare system as a whole. Acupuncture is a relatively inexpensive and quick procedure. Implimentation of this technique may reduce healthcare costs. Additionally, individual subjects may benefit from decreased post-operative pain and experience shorter recovery time.

12.2 RISKS: The only risk of data collection during the study is potential loss of privacy/confidentiality of enrollment in the study. The consents forms with the subject's name will be stored in a locked file cabinet in the anesthesia office area at WAMC. The master link between subject name and ID will be stored in a password protected Excel file on the V drive at WAMC, with access limited to only the study team. This file will be separate from the file containing the collected data,.

12.3 HIPAA AUTHORIZATION WAIVER
If you wish to obtain and use identifiable protected health information for a study without obtaining written approval ("HIPAA Authorization") from the subject, please complete a HIPAA Authorization Waiver Form to provide justification for IRB review and approval. Contact wamcirbadmin@amedd.army.mil for assistance.

13.0 WAIVER OF THE REQUIREMENT TO OBTAIN INFORMED CONSENT:

☐ **The research involves no more than minimal risk to the subjects and,**
The waiver will not adversely affect the rights and welfare of the subjects and,
The research could not practicably be carried out without the waiver.

☒ Not applicable

13.1 WAIVER OF THE REQUIREMENT TO DOCUMENT INFORMED CONSENT:

☐ 1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

☐ 2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

☒ 3. Not applicable.

14.0 IMPACT STATEMENTS:

Department/ Service	Necessary for Which Proposals?	Indicate if this is required for your study.
Information Management Directorate (IMD)	Study involves use of the Internet and/or E-mail for patient recruitment and/or data collection; use of Web page design, data collection, or other Web-based applications	☐Yes ☒No
Laboratory	Study involves laboratory staff or resources	☐Yes ☒No
Nursing	Study requires any involvement of Nursing personnel paid by WAMC	☐Yes ☒No If yes, complete the detailed Nursing Impact Statement found on the IRB Web site
Pharmacy	Study uses any drugs, IND or otherwise	☐Yes ☒No
PAD/Medical Records	Study involves review of medical records	☐Yes ☒No
Radiology	Study requires any radiological services	☐Yes ☒No
Other	For example, a specific clinic, service or department	☒Yes ☐NoIPMC

15.0 SIGNATURES:

I verify that the contents of this proposal are accurate and that I have read and agree to comply with the statements above which outline my responsibilities as a Principal Investigator or Associate Investigator.

_____

Principal Investigator Signature
Name and Date: _____

Associate Investigator Signature
Name and Date:

Associate Investigator Signature
Name and Date:

Associate Investigator Signature
Name and Date:

Associate Investigator Signature
Name and Date:

15.1 OTHER SIGNATURES FOR APPROVAL:

I concur with the submission of this proposal to the Clinical Investigation Service for review and approval.

Service Chief Signature
Name and Date:

IRBNet Number: 381600-19
PI: Dr. Anthony Plunkett
Protocol Title: **A randomized, single-blind, prospective trial of auricular acupuncture for the reduction of post-operative tonsillectomy pain in adults.**
Initial Date Submitted: 6/13/2013
Revision Date: 7/17/17
Department Chief Signature
Name and Date: _____

Checklist of Support Documents that Must Accompany Protocol

__ 1. **Protocol Application** Submit the entire protocol as a word document without signatures in order to allow track changes. Section 15 is the signature page(s). After it is completed, scan in as a pdf file and submit these pages as a "signature" file. Alternatively, you can submit a digitally signed word document.

__ 2. **General Impact Statement** Required on all research protocols. If you answer yes, you must provide a more detailed Impact statement.

__ 3. **Complete Specific Impact Statement as applicable:** Unsigned word documents are not required for these items.

a. Information Management Directorate (IMD)
b. Laboratory Impact Statement
c. Nursing Impact Statement
d. Pharmacy Impact Statement (required if study uses any drugs, IND or otherwise)
e. Pathology Impact Statement
d. Radiology Impact Statement
e. Examples may include specific clinic or service.

__ 4. **Consent Form if applicable** See section 13.0-13.1 above. Contact wamcirbadmin@amedd.army.mil for assistance.

__ 5. **HIPAA Waiver Form if applicable**

__ 6. **Figures / Graphs / Appendices**

__ 7. **Data Collection Sheets / Questionnaire**

__ 8. **Letters related to loaned equipment**

__ 9. **Memorandum related to acceptance of gift/donation**

__ 10. **Cooperative Authorization and Development Agreement (CRADA)** If receiving outside funding, contact wamcirbadmin@amedd.army.mil for assistance. The Clinical Investigations Regulatory Office has final approval of this study.

__ 11. **Conflict of Interest Statement** Must be completed for ALL Investigators

__ 12. **Advertisement Request**

__ 13. **Responsibilities of Principal Investigator and Associate Investigator** Section 3 and 16-18 must be signed.

__ 14. **Copy of Curriculum Vitae (CV)** From Principal Investigator and all Associate Investigator(s). The IRB may request CVs from Collaborators depending on their role in the study.

__ 15. **Certificate on Human Participant Protections Course for all Investigators** Access at http://www.citiprogram.org/. Select New Users or login using previous username/password. Select Womack Army Medical Center as the Participating Institution. Training is good for 3 years.