INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

Title of Project:
Does the use of a nerve stimulator improve the outcome of ultrasound-guided supraclavicular block (anesthesia) for upper extremity surgery?

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1.0 Research Introduction

1.1 Purpose/Specific Aims

We propose to compare the use of a nerve stimulator for ultrasound-guided supraclavicular block (test treatment) to the standard treatment where nerve stimulators are not used (standard treatment) for patients undergoing upper extremity surgery. The block is routinely performed to provide analgesia to the upper limb prior to surgery The hypothesis is that using the nerve stimulator in conjunction with the ultrasound will provide a more accurate method of performing the supraclavicular block. This should result in better outcomes, including improved onset time of analgesia and improved pain control during and after surgery. There is no increased risk to the patients participating in the test treatment group compared to those in the standard treatment.

A. Objectives

The objectives of the study are to demonstrate a difference in quality and effectiveness of analgesia (completeness of pain relief), or extended duration of block as a result of the addition of a nerve stimulator in the performance of the block.

B. Hypotheses / Research Question(s)

The hypothesis is that using a nerve stimulator will improve the effectiveness, quality, and outcome of ultrasound guided supraclavicular blocks.

1.2 Research Significance *(Briefly describe the following in 500 words or less):*

Supraclavicular (above the collarbone) block is a popular anesthetic technique for upper extremity surgery. Historically, this technique utilized anatomically guided needle placement for proper distribution of the anesthetic, but it carried the risk, among others, of pneumothorax. This risk was significantly reduced by the use of ultrasound guidance for needle placement. We propose to further improve the efficacy of this now standard regional block technique by using a nerve stimulator in addition to ultrasound visualization.

1.3 Research Design and Methods

A. Order of occurrence of research procedures

The research procedure involves use of the nerve stimulator technology of the blockade monitor

The study is designed to compare the effectiveness of using a nerve stimulator in conjunction with ultrasound guidance when performing a supraclavicular block. Nerve stimulators have been used for

many years in the performance of various peripheral nerve blocks. With the advent of ultrasound technology, a majority of practitioners have abandoned the use of nerve stimulators and perform these blocks with the ultrasound as the only method of confirming needle location. There have not been many studies to compare the onset, quality, or duration of ultrasound guided supraclavicular blocks with or without the use of a nerve stimulator.

We propose a randomized study design, based on two groups (standard and test treatments). All patients between the ages of 21 and 89 that can communicate in English and meet the selection criteria that are scheduled for upper extremity surgery are eligible to participate.

After consenting to the study, the patient will be randomly assigned to one of two groups, standard or test treatment.

<u>Patients in both groups will receive:</u>

- IV placement on the non-surgical arm with IV fluid infused at 1 ml/kg/hr
- Oxygen by nasal cannula
- Sedation with Midazolam
- Oximetry and EKG monitoring
- Ultrasound-guided supraclavicular block performed as follows:
    - After adequate IV sedation, chloroprep antiseptic solution will be applied to sterilize the injection site.
    - The Sonosite ultrasound probe will be placed in a sterile wrapping and used to identify the subclavian artery as it transverses the upper thorax in the fascia superior to the apex of the lung.
    - The skin overlying the superior aspect of the ultrasound-identified site will be anesthetized with 1% Lidocaine.
    - Through the anesthetized area, a Braun 4 x 21 Stimuplex needle (#4894260) will be inserted and using ultrasound guidance, directed to the area surrounding the subclavian artery.

- In the Standard Group, in the absence of paresthesia and after negative aspiration, the 40 ml of local anesthetic block will be administered.

- In the Test Group, the Braun DIG –R-C Stimuplex blockade monitor system will be initially set at 1 milliamp as the needle approaches this area. As the proximity of the tip of the needle to the components of the brachial plexus becomes evident by ultrasound approximation and the stimulation pattern of the hand and wrist, the output of the system will be reduced to .3-.5 milliamps. In the absence of paresthesia and after negative aspiration, the 40 ml of local anesthetic block will be administered.

- Description of Braun DIG-R-C Stimuplex Blockade Monitor
  This monitor is a nerve stimulator used for locating peripheral nerves in regional anesthesia and pain therapy. It is a class IIa medical device. During the performance of a regional block, as the needle tip approaches the nerve, there appears a muscle twitching in the appropriate muscle group.. This is not painful to the patient. The stimulus is adjusted to estimate the proximity of the needle to the nerve bundle. As the output of the impulse generator is turned lower, there will still be twitching at close range to the nerve. This is the ideal injection point as the device indicates that the stimulus is so low that the needle tip is not within the nerve sheath itself, but instead close to the nerve. This is one way to safely determine how close to a nerve the needle is, without entering the nerve. Only the subsequently injected medicine will enter the nerve, providing an additional element of safety.

B. Data point collection

- During the performance of the block, when the stimulation pattern is still evident at the lower output of the block monitor, the pattern of the movement of the hand will be recorded
- Patients in both groups will be assessed every 5 minutes for the quality of the block, ending at 20 minutes post block. This will involve 4 data points.
- Assessment includes **(See data collection sheet):**
  - response to strength testing of the upper extremity
  - response to hot and cold discrimination with an alcohol pad

response to fine touch provocation

Data points for all subjects will be taken during and after surgery to assess:

1. Speed of onset of the block
   (At 5 min intervals, subjects will be asked to flex their arm against gravity to determine onset of the block).
2. Assessment of intraoperative quality of the block
   (Beginning 5 minutes after the placement of the local anesthetic, and at 5 min intervals, subjects will be asked to distinguish hot and cold and fine touch in the dermatomes of the shoulder and hand. They will have the opportunity to express inadequacy of the block at which time they will receive additional anesthetic in the form of IV supplement or general anesthesia.
   - Duration of block
     (At 30 min intervals post op, subjects will be evaluated for sensory and motor function as compared to the contralateral (opposite) arm, or compared to their preoperative evaluation. Two evaluations will be done, each taking approximately 5 minutes

C. Duration of study and length of time the participant will participate

The duration of the study will be 2 years

The study participant will be assessed during the injection and for 20 minutes after the injection for the block itself and the duration of the entire research data collection would be thirty minutes

1.4 Preliminary Data

There has no comparison of the data collected at this time

1.5 Sample Size Justification

For investigation of improved onset time of analgesia, a smaller sample of 34 subjects in each group (N1=34, N2=34) will be sufficient to maintain 80% power and 0.05 alpha level of statistical significance to show 35% decrease in onset time from 20 min to 13 min (effect 0.7) to achieve the Supraclavicular Block with combined use of ultrasound and nerve stimulator.

According to classic studies Williams et al 2003 (doi: 10.1213/01.ANE.0000086730.09173.CA), onset of sensory block parallels onset of partial motor blockade and was 14+/-6 vs 18+/-6 min for ultrasound-guided vs nerve-stimulator guided supraclavicular block.

This was calculated using the power calculation for sample size for continuous outcomes as the dependent variable and two independent samples for the independent variable.

Accrual rates should be about 50% of the available upper extremity renal transplant / vascular graft procedures which should happen at a rate of 2-4 per week.

However, for observation of qualitative data, we decided on a sample size of 100 (N1=50, N2=50).

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The only difference (the intervention) between the study groups involves the use of the nerve monitor during the performance of the block

The performance of the block with both the ultrasound and the nerve monitor is in excess of the standard of care which utilizes the ultrasound alone , but the needle used for the block is the same in both groups. It is the Stimuplex Teflon coated needle which can be used with or without application of the nerve monitor function

B. Dependent Variables or Outcome Measures

I have expectations that the use of the nerve block monitor will result in a faster speed of onset of the block as the performance characteristics of the block placement relative to the target nerve may be improved.

Dependent variable would be success of the block as measured objectively by speed of onset.

1.7 Drugs/Devices/Biologics

N/A

1.8 Primary Specimen Collection

N/A

1.9 Interviews, Focus Groups, or Surveys

N/A

1.10 Timetable/Schedule of Events

The data collection will take less than 30 min. per patient.
We anticipate it will take two years to accrue 100 participants and complete the study recruitment.

2.0 Project Management

2.1 Research Staff and Qualifications

All investigators will provide documentation of completing CITI training for research on human subjects.

All licensed physicians involved with the study will be competent in the administration of ultrasound-guided supraclavicular blocks under the guidance of the attending anesthesiologist.

All investigators are staff MD in the anesthesia department accustomed to the performance of the supraclavicular block

2.2 Resources Available

All staff have reviewed the protocol and their functions in the study

2.3 Research Sites

The research will be conducted in the RWJ Barnabus facility

3.0 Multi-Site Research Communication & Coordination

N/A

3.1 Outside Research

N/A

4.0 Research Data Source/s

4.1 Primary Data-Subjects and Specimens

N/A

4.2 Subject Selection and Enrollment Considerations

A. Recruitment Details

Recruitment will entail a discussion about the study including, but not limited to, description and purpose of the study, and risks and costs to the patient. Patient will be given ample time to make a decision for their consent.

Patients will be recruited during their visit at the Pre-Admission Clinic or at the Holding Area prior to entering the Operating Room.

For patients sent to the Pre-Admission Clinic by their Surgeon, they are seen at least 48 hours before their scheduled day of surgery. During this time, recruitment is discussed. These patients will have at least 48 hours to contemplate their decision. Prior to entering the Operating Room, their consent will be finalized at the Holding Area.

For patients who arrive from their home, including those scheduled to go home or stay in the hospital after surgery; they arrive at the Holding Area at least 1.5 hours prior to their surgery. During this time, patients will be recruited and given at least 30 minutes to contemplate their decision and finalize consent.

For patients who are already in the hospital and are scheduled for surgery, they arrive at the Holding Area at least 1 hour prior to their surgery. Like the patients who arrive from home, they are given at least 30 minutes to contemplate their decision and finalize consent.

B. Source of Subjects

Patients will be recruited during their visit at the Pre-Admission Clinic or at the Holding Area prior to entering the Operating Room.

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C. Method to Identify Potential Subjects

Potential subjects are patients who are scheduled for elective upper arm surgery, who will undergo ultrasound-guided supraclavicular block between the ages of 21 and 89, and are not excluded by the exclusion criteria.

D. Subject Screening

Patients will be told about the research study: its description, objectives, risks and benefits, its cost to the patient, and the patient's right to change their mind at any time. This will be done by an RWJUH anesthesiologist or anesthesiology resident at the Pre-Admission Clinic or Holding Area.

- **Inclusion Criteria**

All patients scheduled for elective upper arm surgery with ultrasound-guided supraclavicular block between the ages of 21 and 89 years are eligible to participate if they are able to consent to the study and the performance of the supraclavicular block.

These patients will most likely have chronic renal disease requiring creation / repair of AV fistula / grafts. However, other patient populations can be recruited as well if they meet inclusion criteria, and these characteristics should not affect relevancy of the outcome variables for the supraclavicular block.

- **Exclusion Criteria**

The following patients are excluded from this study:

1. Patients unable to communicate in English
2. Pregnant women
3. Persons with allergies to local anesthetics
4. Persons with infection at or near site of needle insertion
5. Patients with severe disturbance of cardiac rhythm and heart block
6. Patients with severe respiratory compromise
7. Patients requiring bilateral upper extremity anesthesia
8. Patients with coagulopathy or medical anticoagulation
9. Patients with traumatic nerve injury to neck or upper extremity
10. Patients with preexisting neurological deficits in the distribution of the block
11. Patients with previous surgery to the neck that may distort brachial plexus anatomy.

Exclusion criteria include contraindications or relative contraindications to supraclavicular blockade. Pregnancy is excluded because of high neonatal blood levels of amide local anesthetics due to placental transfer and impaired elimination with possible fetal bradycardia and acidosis.

The drug under study is known to cause birth defects in some animals. It is likely that it may also cause birth defects in people. For this reason, no one can be in this study who is pregnant or who could get pregnant while taking the study drug. Any woman of childbearing age and are sexually active, are asked about the possibility of being pregnant, and may be asked to give a urine sample for a pregnancy test prior to the procedure and the surgery.

The pediatric population is excluded because children are unlikely to understand the study design, give informed consent/assent, and be cooperative during performance of regional anesthesia.

Patients should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless they tell the study doctor and get permission from the study doctor to go on taking these medicines.

E. Recruitment Materials

N/A

F. Lead Site Recruitment Methods

N/A

4.3 Subject Randomization

Subjects will be randomized into 2 treatment groups. The experimental group (n=50) will receive an ultrasound guided supraclavicular block performed with a nerve stimulator. The control group (n=50) will receive the standard treatment for an ultrasound guided supraclavicular block).

4.4 Secondary Subjects

N/A

4.5 Number of Subjects

A. Total Number of Subjects

Locally, we shall aim to recruit a sample size of 100 subjects (N1=50, N2=50).

B. Total Number of Subjects If Multicenter Study

Not applicable since this is not a multicenter study.

C. Require Number of Subjects to Complete Research

Total number of subjects required would be 64, however, we shall aim to complete a sample size of 100 subjects.

D. Feasibility of Recruiting

We anticipate that the renal transplant / vascular services may have between 2-4 patients per week, of which we may be able to recruit half of them. Therefore, approximately 100 patients per year may be recruited, and it is feasible to complete the study within the proposed recruitment period.

4.6 Consent Procedures

A. Consent

- **Documenting Consent**

We will document informed consent in writing.

- **Waiver of <u>Documentation</u> Of Consent**

We will document informed consent in writing.

- **Waiver or <u>Alteration</u> of Consent <u>Process</u>**

(i) Waiver or <u>Alteration</u> Details

N/A

(ii) Destruction of Identifiers

N/A

(iii) Use of Deception/Concealment

N/A

B. Consent Process

- **Location of Consent Process**

The consent process will take place at the patient's bedside in the holding area or the area where the block will be performed, while the patient still has capacity for consent. Usually it will take place at the same time as the consent for the anesthetic and the supraclavicular nerve block.

- **Ongoing Consent**

The patient's ongoing consent is implied as long as the patient remains cooperative during the performance of the supraclavicular nerve block. There is no ongoing intervention requiring consent after the block is placed.

- **Individual Roles for Researchers Involved in Consent**

1. Consent Discussion Duration

The consent process and discussion will take place within approximately 30 mins after the patient has consented to the anesthetic and the supraclavicular nerve block. It will last approximately 15 mins.

2. Coercion or Undue Influence

The patient will be of capacity to consent. The patient will be assured that an appropriate anesthetic will be performed regardless of the method used to achieve supraclavicular nerve block. Since every patient will be under the care of an attending anesthesiologist, anesthesia will be ensured to be adequate even in the case that onset, duration, or adequacy of the nerve block is inadequate.

Subjects can be removed from the study immediately any time during or after the intervention or the performance of the supraclavicular nerve block if they express desire to revoke consent or be removed from the study.

3. Subject Understanding

The subject will have a thorough discussion with the anesthesiologist and the recruiter and all questions shall be explained during the consent process.

4.7 Special Consent/Populations

A. Minors-Subjects Who Are Not yet Adults

- **Criteria for Consent of Minors**

Minors will not be recruited for the study since they are excluded due to criteria.

- **Wards of the State**

Since a ward of the state is either a minor or an incapacitated adult, informed consent directly from the subject cannot be obtained. Therefore they are excluded from the study.

1. Research in NJ Involving Minors

N/A

2. Research Outside of NJ Involving Minors

N/A

- **Parental Permission**

Parental permission will not be obtained since minors will not be included in the study. Not applicable to adults.

- **Non-Parental Permission**

N/A

- **Assent Process**

N/A

1. Documentation of Assent

N/A

- **Non-English Speaking Subjects**

Any prospective subject that meet inclusion criteria will be introduced to the study in their native or preferred language. Common languages in the recruitment area include Spanish but any languages of course can be spoken by the subjects.

1. Process for Non-English Speaking Subjects

Oral information and discussion will be had with prospective subjects in their native or preferred language through the recruiter using a translator, using a phone system if necessary. Such information will be documented in the consent document.

- **Short Form Consent for Non-English Speakers**

B. Adults Unable to Consent / Cognitively Impaired Adults (*for interventional studies*)

- **NJ Law-Assessment of Regaining the Capacity To Consent**

Since the attending anesthesiologist performing the anesthetic in the operating room for the surgery will not be involved in the recruitment, selection, or performance processes in the study, such an attending physician can assess subjects for the ability to consent. As well, the Anesthesia Officer of the Day can also make such a judgment if there is a conflict in determination of ability to consent.

- **Capacity To Consent**

Consent will always be obtained directly and not via surrogates.

- **NJ Law-Selecting A Witness**

There will be no subjects included in this study using a surrogate consent.
For subjects with direct informed consent, the witness to the consent process shall be a Registered Nurse in the area of the consent process not connected to the study, or another physician in the area of the consent process not connected to the study or the surgical case.

Removing a Subject

Subjects can be removed from the study immediately any time during or after the intervention or the performance of the supraclavicular nerve block if they express desire to revoke consent or be removed from the study.

4.8 Economic Burden and/or Compensation for Subjects

A. Expenses

There is no additional cost to participants undergoing upper extremity surgery, however future patients may benefit from better anesthesia and pain control during the procedure. This study does not address prevention.

B. Compensation/Incentives

There will be no provided compensation / incentives for the subjects.

C. Compensation Documentation

N/A

4.9 Risks to Subjects

A. Description of Subject Risk

There is no additional risk to the subjects since the adequacy of the anesthetic will be assured by an attending anesthesiologist assigned to the surgical case. There is very little risk to the patient even if the onset time of supraclavicular block varies.

B. Procedures for Risks to Embryo, Fetus, and/or Pregnant Subjects

N/A

C. Risks to Non-Subjects

There are no risks to non-subjects.

D. Assessment of Social Behavior Considerations

There is no socio-behavioral risks to the subject using the intervention.

- **Reasonably Foreseeable Risks**

  The only reasonably foreseeable risk involving discomfort to the subject would involve an additional non-painful sensation related to nerve stimulation and involuntary muscle contraction in the subjects randomized to nerve blockade with a nerve stimulator.

  Risk Of Imposing An Intervention On Subject With Existing Condition

  There is no applicable risk to subjects with existing conditions due to the usage of either ultrasound guidance or peripheral nerve stimulator.

- **Other Foreseeable Risks**

  There are no other foreseeable risks.

- **Observation And Sensitive Information**

  Individuals will not be able to be identified using the information connected. There will be no loss of confidentiality.

E. Minimizing Risks

The intervention will be described to the subject so the subject can anticipate the steps involved in the performance of either ultrasound guided or nerve stimulator guided supraclavicular block. There are no inconveniences to the subject. The risks are very low and already minimized.

F. Certificate of Confidentiality

N/A This is not an NIH study.

G. Potential Benefits to Subjects

Potential benefits to subjects may include faster onset of adequate blockade and anesthesia using supraclavicular nerve block if the intervention would decrease onset time of block.

H. Provisions to Protect the Privacy Interests of Subjects

The privacy interests of subjects will be protected since we will securely store all information related to the subject in the study, and the subject cannot be identified using information collected during the study.

I. Research Team Access to Subject Data

Data relating to the study will be collected using paper tabulation and saved in a locked and secure location / cabinet in the office of the Principal Investigator.

4.10 Secondary Data – Records/Chart Reviews/Databases/Tissue Banks/etc.

N/A

4.11 Chart/Record Review Selection

Since the patient will already have been cleared for the procedure by the surgical and anesthesia team and preoperative testing, the patient will have already been determined to be appropriate for surgery. The attending anesthesiologist for the surgical case and the regional block service anesthesiologist together will have determined that the patient is appropriate for the block before they patient meet inclusion criteria. Therefore EMR's do not need to be reviewed. The patients need to be identified as to inclusion and exclusion criteria by a brief discussion with the patient and the anesthesiologist who evaluated the patient for the surgery.

We will not abstract any data from the medical record since data recording will be done in the holding area or area where the block is performed as block adequacy can be assessed.

4.12 Secondary Specimen Collection
Specimen will not be collected.

A. N/A
B. N/A

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
We will not be obtaining, creating, using, and/or disclosing individually identifiable health information associated with a HIPAA-covered component or entity in the course of the research.

5.2 Family Educational Rights and Privacy Act (FERPA)
Student records will not be accessed.

5.3 NJ Access to Medical Research Act
N/A

5.4 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
These specific populations are excluded from the study.

A. "**Special" Classes Of Subjects**
- ***(1)*** *Pregnant Women: see guidance (HRP-412)*
- ***(2)*** *Neonates: see guidance (HRP-413)*
- ***(3)*** *Neonates of Uncertain Viability: see guidance (HRP-414)*
- ***(4)*** *Prisoners: see guidance (HRP-415)*
- ***(5)*** *Children: see guidance (HRP-416)*
- ***(6)*** *Cognitively Impaired Adults: see guidance (HRP-417)*

6.0 Research Data Protection and Reporting

6.1 Data Management and Confidentiality

A. Aggregated and de-identified data from paper documentation will be input into an SPSS data file, secured on a password-protected computer kept in the P.I.'s locked office and secured by Rutgers-RWJMS access code. Group data will be analyzed using descriptive statistics, t-tests and ANOVA. Results will be evaluated by the P.I. in consort with the co-investigators to determine whether this clinical trial supports a larger study.

B. *Difference in time of supraventricular block with ultrasound compared to without is 20 and 13 min, respectively with a standard of deviation of 10. This gives an S/N ratio of 0.65. The alpha will be set to 0.05, the power will be set to 0.80. This gives a necessary sample size of 33 for each group. 50 in each group will be sufficient.*

C. Separation of identifiers will be used for each patient. *Data will be stored on a secure cloud.*

D. Data entry will be handled by the PI. 10% of the flow sheets will be reentered by a second clerk, Scott Mellender, MD, who is a member of the research team and the entries compared for accuracy. If there is more than a 1% difference in data entry, the data will be corrected and the test repeated with another 10 percent of the remaining flow sheets. This process will be repeated until there is a less than 1% disparity between the two data entry processes.

E. All data will be gathered using the same data form (Appendix A). Flow sheets of data will be kept in the P.I.'s locked office. Subjects will be identified by a study number and a copy of the data flow sheet given to the data entry clerk. Data analysis of the confidential data set will be performed by the fellows.

6.2 Data Security
As above

6.3 Data and Safety Monitoring
Research does not involve more than minimal risk.

6.4 Reporting Results

A. Sharing of Results with Subjects
No data will be shared with subjects or others.
B. Individual Results
N/A
C. Aggregate Results
N/A
D. Professional Reporting
We plan to publish in reputable articles as well as present at major pain conferences.
E. ClinicalTrials.Gov Registration and Data Reporting
N/A

Notifying participants of their individual results:

Patients will not be notified of their individual results. If patients inquire about the study, they may have access to the collective data for up to 6 years after surgery. The data will be maintained by the P.I. in his office.

Notifying participants of study findings:

Patients will not be notified of the study findings.

Anticipated products or inventions resulting from the study and their use:

None

Disseminating results to public:

We will present the results for review at professional pain and anesthesia meetings, and possibly for journal publication.

6.5 Data Sharing
No sharing of data to other providers.

7.0 Data and/or Specimen Banking
Data will be stored on a secure hard drive with no patient identifiers.

8.0 Other Approvals/Authorizations
School Site Authorization

9.0 Bibliography

1 - Sauter, Axel R., Michael S. Dodgson, Audun Stubhaug, Anne Marie Halstensen, and Oivind Klaastad. "Electrical Nerve Stimulation or Ultrasound Guidance for Lateral Sagittal Infraclavicular Blocks: A Randomized, Controlled, Observed-Blinded, Comparative Study." *Regional Anesthesia* 106.6 (2008): 1910-915. Print.