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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: *Does the use of a nerve stimulator improve the outcome of ultrasound-guided supraclavicular block (anesthesia) for upper extremity surgery?*

This consent form is part of an informed consent process for a research study and it will give information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor (the principal investigator) or another member of the study team (a co-investigator) will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

The study doctor is interested in finding out if you can fully understand the information you are being given. You need to fully understand the information before you can give your informed consent to enter into this research study.

Why is this study being done?

This study is to help determine if there is improved pain relief when a device that makes an arm muscle move (nerve stimulator) is used to place a needle in the area above the collarbone (supraclavicular nerve block) to prevent feeling of pain (anesthesia) of the upper arm. A nerve stimulator uses short electric pulses to cause a muscle to contract. Above the collarbone (Supraclavicular) blocks are used to prevent feeling of pain (anesthesia) for surgery below the shoulder.

Why have you been asked to take part in this study?

You are asked to be in this study because you are having surgery on the arm for which anesthesia is necessary.

Who may take part in this study? And who may not?

Patients ages 21 – 89 who are having a surgery to the upper arm at Robert Wood Johnson University Hospital Operating Room, are requested to participate.

Patients excluded

- are those who are not able to speak English
- have problems with bleeding
- are allergic to local anesthetic medicine
- have abnormal heart rhythm or cannot breathe well
- have infection on the arm or shoulder
- have a problem with nerve function that affects moving the arms or hands
- have swelling of the arm
- have had previous neck surgery
- are pregnant

How long will the study take and how many subjects will participate?

One hundred patients will participate from RWJ.
This study could take up to 24-months based on the number of upper extremity regional blocks currently performed.

What will you be asked to do if you take part in this research study?

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.

The block will be performed for the arm which is going to have surgery. The upper chest and arm will be prepared in a sterile fashion with antiseptic solution. You will be asked to remain still and not to touch the sterile areas. You will get numbing medication (local anesthesia) through a very small needle in the skin over the area where the block will take place so that you will not experience pain during the placement of the block. Ultrasound guidance will be used to properly place the needle. The medical doctor placing the block will place the block in the standard method that is used by our department. The only difference in the study groups will be the additional use of a nerve stimulator in one of the study groups. A nerve stimulator uses short electric pulses to cause a muscle to contract. After the block is placed successfully, the arm will become numb and heavy, and you will be unable to move the arm during your surgery, and for a total of approximately 4 hours.
At 5 min intervals, after injecting the numbing medication, you will be asked to flex arm arm against gravity to determine when the medication started working.
Beginning 5 minutes after injecting the numbing medication, and at 5 min intervals, you will be asked to distinguish hot and cold and fine touch in areas of your skin, of the shoulder and hand.

At 30 min intervals after your surgery, (2 evaluations lasting 5 mins.) you will be evaluated for numbness and ability to flex your arm against gravity as compared to the contralateral (opposite)arm, or compared to their preoperative evaluation.
During all these times, your blood pressure will be recorded at 5 minute intervals on the other arm.

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

You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

What are the risks and/or discomforts you might experience if you take part in this study?

The risks involved with this block will be the same as the standard method of placing this block. The only difference is the addition of the nerve stimulator. With the addition of the nerve stimulator, there are no additional risks known at this time. However, you will feel discomfort of the nerve stimulator contracting your muscles involuntarily, but not pain.

There is a risk of breach of confidentiality, but we take every precaution to secure your privacy and your records.

Are there any benefits for you if you choose to take part in this research study?

You might receive no direct benefit from taking part in this study. However, possible benefits include prolonged pain relief, faster onset of pain relief, and more effective pain relief.

What are your alternatives if you don't want to take part in this study?

The following alternative treatments are available if you choose not to take part in this study:

You can choose not to take part in the study. Non-participation in the study does not affect your ability to have your surgery. You can discuss your anesthetic options with your surgeon and anesthesiologist. If your surgeon requires you to have a supraclavicular block for your surgery, and you wish to proceed with the block and surgery, but not to participate in the study, then the standard method will be utilized.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If new information

is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There is no cost to you to take part in the study.

Will you be paid to take part in this study?

You will **not** receive compensation for your participation in the study.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Records and data will be collected by research team members, and will be stored and maintained by the study doctor in a locked file cabinet for a period of no less than 6 years. The data will be analyzed by the members of the research team, as well as an outside statistician. Original data collection forms will be maintained in a locked storage unit in the PI's office.

What will happen if you are injured during this study?
Medical and/or dental treatment will be arranged by Rutgers-RWJMS for participants who sustain physical injuries or illnesses as a direct consequence of participation in this research. Your insurance carrier or other third party payer will be billed for the cost of this treatment. However, your health insurance company may or may not pay for treatment of injuries as a result of participation in this study. No additional financial payment to you is available.

You are not giving up any of your legal rights by signing this informed consent form or by taking part in this research study.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

You may choose not to be in the study. If you do choose to take part it is voluntary. You may refuse to take part or may change your mind at any time.

If you do not want to enter the study or decide to pull out of the study, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to:

Dr. William R. Grubb DDS, MD
Department of Anesthesia, CAB 3100
Rutgers – Robert Wood Johnson Medical School
125 Paterson Street
New Brunswick, NJ 08901

Any data that has already been sent to the PI, Dr. Grubb or the Co-Investigator, Dr. Kiss cannot be withdrawn but will be maintained in a secure file for 6 years.
At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Dr. William Grubb DDS, MD
Department of Anesthesia, CAB 3100
Rutgers – Robert Wood Johnson Medical School
125 Paterson Street
New Brunswick, NJ 08901
(732)-235-7827

If you have any questions about your rights as a research subject, you can call:
IRB Director
(732)-235-9806 New Brunswick/Piscataway

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____