INFORMED CONSENT FORM

Title of Study

Comparison of the Ultrasound Guided Reginal Anaesthesia (UGRA) with and without Peripheral Nerve Stimulation (PNS) Guidance in achieving Peripheral Nerves Blockade (PNB).

Principal Investigator: Dr. Azhar Rehman, Assistant Professor, Department of Anesthesiology, Aga Khan University Hospital.

Co-Investigator: Dr. M. Azhar Sharafat, Resident, Department of Anesthesiology, Aga Khan University Hospital.

Institute

Department of Anaesthesiology, Aga Khan University Hospital, Karachi.

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Introduction and Background

I, Dr. M. Azhar Sharafat, Resident, Department of Anesthesiology, Aga Khan University Hospital, Karachi, am conducting the above titled research in which we will compare Ultrasound guided regional anaesthesia (UGRA) with and without peripheral nerve stimulation guidance in achieving nerve block and its outcomes. Since you meet our inclusion criteria, I would like to invite you to participate in this study.

Purpose of this Research Study

Peripheral nerve stimulation (PNS) to identify the peripheral nerves was a common practice before the advent and widespread availability of Ultrasound for peripheral nerve blocks, which led to fade in the use of PNS and now it is very rarely used in clinical practice for nerve blocks.

However, recent observations and clinical experiences has shown that Ultrasound guidance may have its own limitations. Such as difficulty in visualization and identifying neural structures, inability to confidently identify and exclude the placement of needle tip within the nerve and etc. Such limitations can potentially be circumvented by using PNS Guidance in conjunction with ultrasound.

So, considering additional potential benefits of PNS Guidance, we are conducting a randomized control trial by comparing the UGRA with and without PNS Guidance in achieving Nerve Blocks and its outcomes.

Furthermore, the results of this study will help us to determine which approach for peripheral nerve blocks is more beneficial and has better patient related outcomes. The successful practice could then be recommended in clinical settings.

Procedure

If you agree to be a part of this study, you will be a part of the study from the start of anaesthesia till being discharged from the Post Anaesthesia Care Unit. You will be randomized with the help of computer-generated blocks into either of the following two groups:

- **Ultrasound Group:** Ultrasound imaging will be used to locate the brachial plexus in the supraclavicular region. Local anaesthetic will then be infiltrated in the subcutaneous plane to decrease the discomfort during block. Afterwards, block needle will be introduced under ultrasound guidance and brachial plexus will be blocked with infiltration of local anaesthetic. You will be monitored after wards for the effect of block by using ice to check for sensory loss, and muscle power in the upper limb to check for motor loss.
- **Ultrasound plus Peripheral Nerve Stimulation Group:** Ultrasound imaging will be used to locate the brachial plexus in the supraclavicular region. Local anaesthetic will then be infiltrated in the subcutaneous plane to decrease the discomfort during block. Afterwards, block needle will be introduced under ultrasound as well as peripheral nerve stimulation guidance and brachial plexus will be blocked with infiltration of local anaesthetic. You will be monitored after wards for the effect of block by using ice to check for sensory loss, and muscle power in the upper limb to check for motor loss.

Possible Risks

You may experience some discomfort during the Nerve block procedure but that will only last for a very short period of time.

There are some known side effects of the procedure and drugs being used in the block such as difficulty in breathing, low blood pressure, nausea/vomiting, drowsiness and block failure. Very rare complication of the procedure include pneumothorax, horner's syndrome, nerve injury, inadvert intravascular injection and local anaesthetic systemic toxicity. However, the rate of such complication has been reduced to less than 1% since the use of ultrasound imaging for block administration. Any such immediate side effect and complication will be recorded and managed by the primary anaesthetist. Majority of these complications are benign and does not require active management other than close observation. Intravascular injection of local anaesthetic and its systemic toxicity will be treated according to the current anaesthesia practice guidelines by managing blood pressure, heart rate and breathing all the while administering its antidote.

There will be no extra charges for the procedure that we are going to carry out. We will be paying for the needles and drugs used in this procedure and any expanse related to study related complication; hence no extra cost will be transferred to you.

Alternative Treatment

If you do not want to participate in this study the standard of care provided to you will remain same.

Financial Considerations

There is no financial compensation for your participation in this research. There are no financial implications for the study subjects.

Confidentiality

The information provided by you will remain confidential. Nobody except the principal investigator and the team members will have access to it. Your name and identity will also not be disclosed at any time. However, the data may be seen by the Aga khan university Ethical Review Committee and may be published in a journal and elsewhere without giving your name or disclosing your identity. Codes for identifying data will be given to entries on SPSS (statistical package for the social sciences) to protect confidentiality.

Right of Refusal to Participate and Withdrawal

You are free to choose whether to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during this study that may relate to or influence your willingness to continue participation.

Available Sources of Information

Any further questions you have about this study or about your rights will be answered by the Co-Investigator: Dr. M. Azhar Sharafat (0318-2383353).

In case of you wish to know more about your legal rights or in case of any injury during the study you may contact the Ethical Review Committee at the Aga Khan University Karachi at 021-34864880. If you wish to know the compiled results after the completion of the study, please mention your email address or phone number here:

Authorization

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Participant's name: _____

Participant's signature/thumb impression: _____

Date: _____

Primary investigator's/Co-investigator's signature: _____

Date: _____

Signature of the person obtaining consent: _____

Date: _____

Name of the witness: _____

Signature of the witness: _____

Date: _____-