Research Informed Consent form

Title: Identification of Epidural Space: A Comparison Study Between Contrast Spread and Loss of Resistance Techniques

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RESEARCH CONSENT FORM

Protocol Title: *Two-sample paired t-test on epidural space identification: contrast spread technique vs loss of resistance technique with 18G or 25G Tuohy needles.*

READ THE FOLLOWING CAREFULLY

You are being asked to volunteer in a study to help doctors identify the best method for finding the optimal spot for administering an epidural anesthetic. Before you give your consent to be part of the study, please read the following and ask as many questions as necessary to be sure that you understand what your participation will involve.

YOUR RIGHTS

1. You do not have to participate in this study. If you do decide to participate, you may withdraw at any time without affecting your quality of care. Declining or withdrawing from the study will not affect your medical care or remove any benefits you might otherwise be entitled to. **Your wellbeing is always more important than the study. If you no longer wish to be in the study, all you have to do is tell your doctor you wish to stop.**
2. You are entitled to have adequate time to consider the material in the consent and decide on participation or not.
3. You are entitled to have your questions answered to your satisfaction.
4. If you do not understand words or information in the consent, you are entitled to an explanation in terms that you understand.

YOUR RESPONSIBILITIES

1. You are required to disclose use (and change in use) of any prescribed or over-the-counter medications, any change in your health or any accident to the Study Doctor.
2. You are required to give truthful and complete information about your medical history. Giving false, incomplete, or misleading information about your medical history could have serious health consequences.
3. If you have suffered an illness or an adverse event, the study Doctor needs to be aware. In addition, you should inform any doctor you visit of your participation in the study.

PURPOSE OF THE STUDY

Epidural anesthesia is a well-established procedure to block pain. Identifying the exact spot (epidural space) to insert the needle is a crucial element of an effective block. This study will compare the reliability of epidural space identification of two different techniques while performing cervical epidural injection with either 18G or 25G needles.

PROCEDURES

You will be taken to the procedure room where the cervical epidural steroid injection will be performed. After sterile prep in the usual manner, a local anesthetic will be injected at the point of the injection. An 18-gauge or 25-gauge epidural needle will be inserted, and then placed close to the epidural space under fluoroscopy.

Later, an epidural space will be identified, first with contrast spread technique, and then with the loss of resistance technique. After the epidural space is confirmed with the injection of contrast, a 2 ml solution of 40 mg of Kenalog in normal saline will be injected. After the procedure is completed, you will be taken to the recovery room, and when you are stable, you will be discharged home.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

No additional responsibilities are necessary to take part in the research other than those mentioned above.

POTENTIAL BENEFITS

Taking part in this study may help determine which technique – the contrast spread technique, or the loss of resistance technique recognizes epidural space sooner. This information is essential for decreasing risk and improving the safety of cervical epidural steroid injection.

POTENTIAL RISKS/DISCOMFORTS:

Potential risks of participating in this study include but are not limited to:

- Longer duration of the procedure. Instead of 3-5 minutes, it may take 5-10 minutes.
- Higher exposure to X-rays. However, this increase is insignificant, and X-ray time will not exceed the average fluoroscopy time for cervical epidural injection.
- There are several intrinsic risks related to the cervical epidural injections, such as infection, bleeding, and risks due to the steroid injection, nerve damage, and even death. However, those risks are not increased with participating in the study.

ALTERNATIVES TO PARTICIPATION

You have the choice to not participate in this study. If you choose not to take part, Dr. Perper will perform the cervical epidural injection in the regular way.

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PAYMENT TO PARTICIPANTS

Participants will not be paid for participation in this study.
Medical staff will be on hand to treat any research-related injuries that may occur.
There will be no compensation provided for a research-related injury.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve accessing confidential information in the participant's medical record, such as age, and gender. This information will be de-identified and kept in a locked office on a password-protected computer. Only the study investigators will have access to this information.

Any paper records (i.e. Consent forms) will be kept securely in a locked cabinet in the office of our research staff. Only they will have access to these records.

The data from this study may be published, however, you will not be identified by name. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research if you do not want to.

You are free to withdraw your consent at any time. If you decide to depart early, there is no risk, side effects, or discomfort. Refusal to take part, or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. You do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Dr. Perper at 718-687-2010.

After you decide that you no longer wish to participate, we will remove you from the study, and all of the data related to your care will be removed from this study. Any records related to this study will be destroyed.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

You will receive a copy of this signed consent form.

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SIGNATURES SHOWING AGREEMENT

CONSENT

By signing this form, I agree that:

1) I have fully read and understand this consent form describing this research study.
2) I have had the opportunity to ask questions to one of the persons in charge of this research and have received satisfactory answers.
3) I have been given a signed and dated copy of this consent form, which is mine to keep.
4) I understand that I am being asked to participate in a research study.
5) I am not participating in any other research study at this time.
6) I understand the risks and benefits, and I freely give my consent to voluntarily participate in the research study as outlined in this form under the conditions indicated in it.
7) I understand that I may refuse to participate in the research and I may withdraw at any time.
8) If required, I authorize the release of my medical records to the Food and Drug Administration (FDA) USA.
9) By signing this form, I have not waived any of my legal rights, which I otherwise would have as a participant in a research study.
10) I give permission to the study personnel to obtain my relevant medical records or information from other doctors from whom I receive medical care.
11) I understand that my decision to participate in this study does not free the investigators from their professional and legal obligations toward me.

I will receive a copy of this signed informed consent form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

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INVESTIGATORS STATEMENT: I, or a member of my staff, have carefully explained to the participant the nature of the above protocol (study plan). I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, risks and benefits involved in participating in this study, and that a medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in this study.

_____

Printed Name of Investigator

_____ _____

Signature of Investigator Date