Informed Consent Form

Official Title: Anesthetic Effect of Ropivacaine on Local Infiltration Anesthesia in Arteriovenous Fistula Surgery: a Randomized Controlled Trial

NCT Number: [NCT ID not yet assigned]

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INFORMED CONSENT FORM

Introduction

You are being invited to take part in a research study. This form provides important information about what participating in this study would involve. Please read it carefully and take your time to make your decision.

1. What is this study about? (Purpose)

This study is called: "Anesthetic Effect of Ropivacaine on Local Infiltration Anesthesia in Arteriovenous Fistula Surgery: a Randomized Controlled Trial."

The purpose of this research is to compare two local anesthetics, ropivacaine and lidocaine, which are commonly used for numbing the area during arteriovenous fistula surgery. We want to see which one provides better pain control during and after the surgery and if it leads to better outcomes for your fistula. About 40 people will take part in this study at Lianyungang First People's Hospital.

2. What will happen if I take part? (Procedures)

If you agree to participate:

- You will be randomly assigned (like drawing lots) to one of two groups. One group will receive ropivacaine, and the other will receive lidocaine for local anesthesia during your surgery. You, your surgeon, and the staff assessing your outcomes will not know which medication you receive.
- Apart from the type of local anesthetic used, you will receive all the standard medical care for your surgery.
- We will collect information about your pain levels during and after surgery, how long the surgery takes, if you need any additional pain medicine, and about the function of your fistula after surgery. We will follow up with you at 24 hours, 48 hours, 8 weeks, 1 year, and 5 years after your surgery to check on your progress.

3. What are the possible risks and discomforts?

Both ropivacaine and lidocaine are widely used and generally safe. However, as with any medication and medical procedure, there are potential risks, which may include:

- Allergic reactions to the local anesthetic.
- Bleeding or bruising at the injection site.
- Nerve injury.
- Infection.

The researchers are trained to manage these situations and will monitor you closely throughout.

4. What are the possible benefits?

You might experience better or longer-lasting pain control from the local anesthetic used in the study. The information collected from this study may also help doctors choose the best anesthetic for future patients having similar surgery.

5. How will my information be kept private? (Confidentiality)

Your study records will be handled confidentially. Your name and other identifying information will not be used in any reports or publications resulting from this study. The records will be stored securely, and access will be limited to the research team and regulatory authorities.

6. What are my rights as a participant?

Taking part in this study is entirely voluntary. You can choose not to take part, or you can leave the study at any time, for any reason, without any penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your current or future medical care at this hospital.

7. Whom do I contact if I have questions?

If you have any questions about this study or your rights as a participant, or if you experience any research-related injury, please contact the Principal Investigator at +86 18961322515.

If you have questions about your rights as a research participant, you can contact:
The Institutional Review Board of Lianyungang First People's Hospital at +86 518 8576 7557.

Participant's Statement:

"I have read this consent form, and the research study has been explained to me. I have had the opportunity to ask questions, and my questions have been answered. I voluntarily agree to take part in this study."

Participant's Signature: _____ Date: _____

Investigator's Statement:

"I have explained the research to the participant and answered all questions."

Investigator's Signature: _____ Date: _____