Practice name:
Participant ID:

I N F O R M E D C O N S E N T

Informed Consent form for patient.
This Informed Consent Form is intended for both men and women attending Shanghai Pulmonary Hospital, whom we are inviting to participate in research on postoperative pain management.
The title of our research project is: *Comparison of ultrasound-guided subtransverse process interligamentary plane block with paravertebral block for postoperative analgesia in thoracic surgery*.

Principal Investigator: Hong Shi, MD
Organization: Department of Anesthesiology, Shanghai Pulmonary Hospital, Tongji University School of Medicine

This Informed Consent Form has two parts:
1. Information Sheet (providing details about the research for your understanding).
2. Certificate of Consent (for your signature if you choose to participate).

You will receive a copy of the complete Informed Consent Form.

Wu W, *et al. BMJ Open* 2024; 14:e082135. doi: 10.1136/bmjopen-2023-082135

PART 1: Information Sheet

Introduction

Hello, I am Hong Shi, working in the Department of Anesthesiology. We are currently conducting research on postoperative pain management for thoracoscopic surgery. I'm reaching out to share information with you and extend an invitation for your participation in this research.

There's no rush for you to decide today; take your time to consider it. Feel free to discuss it with someone you trust and feel comfortable talking to about the research.

If you come across any unfamiliar terms or concepts, please feel free to interrupt, and I will take the time to provide explanations. Should you have any questions later on, you can direct them to me, the study doctor, or the staff.

Purpose of the research

Postoperative pain profoundly affects the recovery of patients following thoracoscopic surgery. Hence, we have crafted a comparative study to evaluate the efficacy of two analgesic methods. One involves the conventional paravertebral nerve block, while the other entails the subtransverse process interligamentary plane block. The primary objective of the study is to assess the effectiveness of these methods in postoperative pain management.

Participant selection

We invite all adults scheduled for Video-Assisted Thoracoscopic Surgery (VATS) at Shanghai Pulmonary Hospital to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary, and the decision to participate is entirely yours. Regardless of your choice to participate or not, all the services you receive at this center will continue without any changes. If you choose not to participate in this research project, you will receive the standard treatment routinely offered, and further details will be provided later. Moreover, you retain the option to change your decision and withdraw from participation at any time, even if you initially agreed.

Procedures and Protocol

Participants will be randomly assigned to one of two groups. Participants in one group will undergo Thoracic Paravertebral Block (TPVB), while participants in the other group will receive the Subtransverse Process Interligamentary Plane Block (STIL). We will then compare the outcomes of the two procedures to determine which yields better results.

Healthcare professionals will provide careful monitoring and care throughout the study. If there are concerns about the treatment effects, we will identify the treatment received and make necessary adjustments. If you have any concerns or issues related to the research, please feel free to discuss them with me or any other researchers.

For any clinical study (if relevant):

We will extract blood from your arm using a syringe. This procedure is painless. In total, we will collect approximately 2 samples of 5 milliliters of blood. Any remaining blood samples at the conclusion of the study will be properly disposed of.

Description of the Process

To begin with, we will use a syringe through a catheter to extract a small amount of blood from your arm. This blood sample will be sent to the laboratory for testing. Concurrently, we will inquire about your general health.

Following your induction into general anesthesia, I will administer different blocking procedures, as previously mentioned. One involves the Thoracic Paravertebral Block (TPVB), and the other is the Subtransverse Process Interligamentary Plane Block. These blocking procedures are conducted on your back. Given your state of general anesthesia, you won't experience any sensation during these procedures.

Post-surgery, on the second day, we will once again collect a blood sample from you.

Furthermore, we will conduct several follow-up visits, posing questions about your postoperative well-being. This process is designed to ensure a comprehensive understanding of your physical condition and the treatment's impact.

If you have any concerns or questions about this process, please feel free to contact us at any time.

Duration

The study is anticipated to span approximately 3-4 days, covering the entirety of your hospitalization period.

Risks

The analgesic procedures in both groups are standard practices. Risks are associated with the puncture technique, encompassing typical complications observed in local anesthetic techniques, such as puncture site infections, hematomas at the puncture site, nerve damage, and toxicity linked to an overdose of local anesthetics.

Moreover, specific complications for the paravertebral block include the risk of pneumothorax, hemothorax, or intrathecal injection. The healthcare team will be meticulously monitoring you and the other participants throughout the study. If there are concerns about the treatment's effects, we will identify the treatment you are receiving and make necessary adjustments.

Benefits

By participating in our study, you stand to benefit in several ways: our intervention contributes to alleviating postoperative pain following thoracoscopic surgery, reducing adverse reactions such as nausea, vomiting, and dizziness associated with the use of opioid medications, and facilitating a quicker recovery process.

Additionally, it is important to emphasize that in the unlikely event of any harm resulting from your participation in this study, we are committed to providing complimentary treatment and/or appropriate compensation. We are dedicated to ensuring your safety and well-being, taking all necessary measures to minimize

potential risks.

We appreciate your valuable contribution to our research, which will contribute to advancements in the field of medical science.

Reimbursements

Your participation is free. You will not be given any other money or gifts to take part in this research.

Confidentiality

If you decide to participate in this trial, your involvement and personal information throughout the study will be handled with utmost confidentiality.

The principal investigator and other researchers will utilize your medical information strictly for research purposes. This may encompass details such as your name, address, phone number, medical history, and information gathered during your study visits. Your records will be securely stored in a locked filing cabinet, accessible exclusively to the research team. Identification numbers will be assigned to categorize your research data and laboratory specimens during the study. Access to these identification numbers will be restricted to the researchers and authorized members of the research team.

To ensure adherence to regulations, if necessary, the study sponsor, government regulatory authorities, or ethics review board members may inspect your personal information at the study site as mandated.

When the findings of this study are disseminated, no personal information about you will be disclosed.

Sharing the Results

The insights derived from this research will be communicated to you through clinics or phone discussions before being disseminated to the public, if necessary. Confidential information will remain secure and will not be disclosed.

Ultimately, we plan to publish the research results, allowing other interested parties to benefit from our study.

Right to Refuse or Withdraw

You are not obligated to participate in this research if you choose not to.

Furthermore, you have the option to discontinue your participation at any time. Your decision is entirely yours, and we will continue to respect all of your rights.

Alternatives to Participating

If you choose not to participate in the research, you will receive the standard treatment available at our hospital.

Who to Contact

If you have any questions, feel free to ask them at any time, even after the study has commenced. For inquiries later on, you may contact any of the following:

Dr. Hong Shi, Phone: 86-13651958255

This proposal has undergone thorough review and received approval from the Ethics Committee of Shanghai Pulmonary Hospital, China (Approval No. L22-329). The committee ensures the protection of research participants from any potential harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness or a legally authorized representative must sign. A researcher or the person going over the informed consent must sign each consent. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

		Please initial each box
1	I have read the foregoing information, or it has been read to me.	☐
2	I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.	☐
3	I consent voluntarily to participate as a participant in this research.	☐

Print Name of Participant _____

Signature of Participant _____

Date (Day/month/year) _____

If illiterate

Aliterate witness or legally authorized representative must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

		Please initial each box
1	I have witnessed the accurate reading of the consent form to the potential participant	☐
2	I have witnessed the individual has had the opportunity to ask questions.	☐
3	I confirm that the individual has given consent freely.	☐

Print Name of witness or legally authorized representative _____

Signature of witness or legally authorized representative _____

Date (Day/month/year) _____

Thumb print of participant ☐

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher _____

Signature of Researcher _____

Date (Day/month/year) _____