Informed Consent Form

Official Title: Application of Pre-Emptive Analgesia with Parecoxib Sodium in CT-Guided Hook Wire Localization of Lung Nodules Before Video-Assisted Thoracoscopic Surgery and Exploration of the Optimal Clinical Dosing Window: A Single-Center, Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial

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1. Study Introduction and Purpose

You are invited to participate in a medical clinical research study. Please read this informed consent form carefully before deciding whether to participate. It will explain the purpose, procedures, potential risks, and benefits of this study. If you have any questions, please feel free to ask your attending physician or the research team.

Background: Preoperative CT-guided hook wire localization is an important step for the precise resection of small lung nodules during Video-Assisted Thoracoscopic Surgery (VATS). However, the puncture procedure can cause severe pain, which not only affects your comfort but may also lead to poor cooperation (such as an inability to hold your breath), thereby increasing the risk of complications like wire dislodgement, pneumothorax, and bleeding.

Purpose: This study aims to evaluate whether a pre-emptive intravenous injection of a pain-relieving medication called "parecoxib sodium" (a commonly used non-steroidal anti-inflammatory drug) before the CT localization procedure can effectively reduce your pain during the puncture. Furthermore, we hope to discover the optimal timing for administering this medication prior to the localization to achieve the best analgesic effect.

2. Eligibility for Participation

You are invited to participate if you meet the following conditions:

You are an adult patient aged 18 years or older.

You have been diagnosed with non-small cell lung cancer (NSCLC) and are scheduled to undergo Video-Assisted Thoracoscopic Surgery (VATS).

You require a preoperative CT-guided hook wire localization for lung nodules.

3. Study Procedures

If you agree to participate, you will be randomly assigned to one of two groups:

Study Group (Parecoxib Sodium Group): You will receive a single intravenous injection of 40mg of parecoxib sodium prior to the CT localization.

Control Group (Placebo Group): You will receive a single intravenous injection of an equal volume of normal saline prior to the CT localization.
Since this is a "double-blind" trial, neither you nor your attending physician will know which specific injection you received until the study concludes. This is to ensure the objectivity of the study results. The assignment ratio is 2:1, meaning you have a two-thirds (66%) chance of receiving the pain medication and a one-third (33%) chance of receiving normal saline.

Administration Time: The medication/saline will be administered intravenously by a nurse at a specific time before you go to the CT room for localization (this could be less than 1 hour, 1-3 hours, or more than 3 hours prior). We will accurately record the time of the injection.

Assessment: Immediately after the localization is completed (within 5 minutes after withdrawing the guide needle), researchers will ask you to rate your pain using a Visual Analog Scale (VAS, 0-10 points). We will also record your satisfaction with the procedure, whether you required additional pain medication, and if you experienced any discomfort.

4. Medication Restrictions
To ensure the accuracy of the study, you will not be allowed to use other non-steroidal anti-inflammatory drugs (e.g., ibuprofen) from 24 hours prior to receiving the study injection until the pain assessment is completed. As a general rule, opioid medications (e.g., morphine) are also prohibited, unless you experience severe, unbearable pain (VAS score $\geqslant$ 7) during the localization, in which case the doctor will provide necessary rescue pain relief measures.

5. Risks and Adverse Reactions
Parecoxib sodium is a widely used, mature analgesic medication in clinical practice. This study optimizes the strategy of pre-emptive administration and has an extremely low safety risk. However, any medication may cause adverse reactions.

Common adverse reactions may include: Nausea, vomiting, dizziness, and gastrointestinal discomfort.
If you experience any discomfort or adverse events during the study, please inform the research team immediately. In the event of a severe adverse event, the investigators will immediately take appropriate medical measures.

6. Potential Benefits
If you are assigned to the study group, you may experience less pain during the localization procedure due to the early administration of pain medication, resulting in a better overall experience. However, we cannot guarantee that you will directly benefit from this. Your participation will provide valuable data to the medical community, helping to optimize pain management protocols for future patients.

7. Privacy and Confidentiality
All your medical records and study data will be kept strictly confidential. Any publicly released reports or literature will not contain any information that could identify you personally.

8. Study-Related Costs
Regardless of whether you are assigned to the study group or the control group, the cost of the trial medication (parecoxib sodium or normal saline) involved in this study will be fully covered by the research funding. You will not have to pay any extra fees for the study interventions you receive. Other routine medical expenses related to your standard treatment (such as surgery fees, routine hospitalization fees, etc.) will still be billed according to standard medical procedures.

9. Voluntary Participation and Withdrawal
Your participation is entirely voluntary. You may choose not to participate or withdraw from the study at any time unconditionally after signing the consent form. This will in no way affect your normal treatment or the attitude of your doctors toward you.

Declaration and Signatures
I have read the information above, or it has been read and explained to me. I understand the purpose, procedures, potential risks, and benefits of participating in this study. I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction.

I voluntarily agree to participate in this clinical research study.

Participant's Printed Name: _____
Participant's Signature: _____
Date: _____

Investigator's/Presenter's Printed Name: _____
Investigator's/Presenter's Signature: _____
Date: _____