INFORMED CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

You are invited to participate in a clinical study: **Efficacy of Perioperative Intravenous Lidocaine Infusion on Postoperative Pulmonary Complications in Patients Undergoing Video-Assisted Thoracoscopic Lung Resection Surgery.** The study protocol has been reviewed and approved by the Ethics Committee of **Sichuan Academy of Medical Sciences and Sichuan Provincial People's Hospital**.

Before you decide whether to participate in this study, please read the following as carefully as possible. It will be useful for you to understand the study and why it is being done, the procedures, duration of the study, benefits, risks and discomforts you may experience as a result of participating in the study. You can also discuss it with your relatives and friends, or ask your doctor to explain it to help you make your decision.

**Introduction**

Postoperative pulmonary complications are very common in thoracic surgery and are a major cause of delayed recovery, prolonged hospital stay, and increased mortality in patients in the perioperative period. Lidocaine, as an amide local anesthetic and Ib antiarrhythmic drug, can produce analgesia, sedation, anti-inflammation, reduce intubation stress, promote gastrointestinal function recovery, and organ protection when used intravenously in clinical practice. Prolonged atrophy of the affected lung during thoracoscopic lung resection surgery, disproportionate ventilation and blood flow, mechanical ventilation, and surgical operations can cause damage to alveolar epithelial cells and release of inflammatory substances, resulting in lung injury. Combining the mechanism of lidocaine pulmonary protection and the mechanism of lung injury in patients undergoing thoracoscopic lung resection surgery, we hypothesized that perioperative intravenous lidocaine infusion can reduce the incidence of postoperative pulmonary complications, improve the quality of recovery, accelerate recovery, shorten the length of hospital stay, and improve the medium- and long-term prognosis.

**What will I need to do if I participate in the study?**

1. If you are an eligible participant, you may voluntarily participate in the study by

signing the informed consent form. If you do not wish to participate in the study, we will administer the treatment according to your wishes.

2. If you volunteer to participate in the study, the following steps will be followed.

If you participate in the study, you will be fully briefed by the investigator on the study implementation protocol prior to the start of the study. We will instruct you about the Quality of Recovery 40 (QoR-40) scales (including emotional state, physical comfort, physical independence, psychological support, pain), and assessed after you understand the meaning of the questionnaire. Upon admission to the operating room, your vital signs (including electrocardiogram, blood pressure, oxygen saturation, temperature, etc.) will be routinely monitored and you will be randomly assigned to lidocaine or saline group. At the end of the induction of general anesthesia, an intravenous lidocaine or saline bolus of 1.5mg/kg will be administered, followed by a continuous infusion of intravenous lidocaine or saline at 2 mg/kg/h until the end of surgery. The other drugs are administered during the anesthesia procedure according to the routine management protocol for anesthesia in thoracic surgery. The QoR-40 scales will be used to assess your recovery quality within 24 h after surgery, and we will evaluate your pain degree and whether adverse effects happen (such as nausea, vomiting, itchy skin, constipation and urinary retention). On the other hand, we will assess pulmonary complications such as pneumothorax, lung infection, fluid chest, etc.

**Possible benefits of participating in the study**

By participating in this study, the investigators adequately assessed the occurrence of postoperative pulmonary complications, the quality of recovery, the severity of postoperative pain and analgesic effect, and the occurrence of adverse reactions in perioperative period, and adopted a timely treatment plan to accelerate postoperative recovery, reduce the incidence of complications and adverse reactions, and shorten the length of hospitalization. In addition, the research results are expected to be extended to patients with other types of surgery for the benefit of a wider surgical population.

**Possible adverse effects, risks and discomfort, inconvenience of participating in the study**

During the study, patients may experience lidocaine-related adverse reactions, so we chose a very safe range of lidocaine, and once patients experience local anesthetic

toxicity, they are immediately treated, and all medical costs for treatment are borne by the project team. For any emergencies or questions, participants can contact the clinical investigator at the following contact information: Fei Wang 17882249509.

The QoR-40 scale assessment will take you five minutes. some questions in the questionnaire may be uncomfortable and you can refuse to answer.

If you experience any discomfort, new changes in your condition, or any unforeseen circumstances during the study, whether or not related to the study, you should promptly notify your physician, who will make a determination and give appropriate medical treatment.

**Related costs**

The cost of lidocaine and saline involved in the study is covered by the research group and there is no additional cost to you.

In the event of an adverse reaction, the physician will provide immediate treatment and therapy, while a committee of medical experts will determine whether it is related to the therapeutic drug lidocaine.

Treatment and tests required for other conditions that you also have combined will not be covered at no charge.

**Confidentiality of personal information**

Your medical records (medical record/case report form (CRF), labs, etc.) will be kept intact at hospital. Your doctor will record the results of labs and other tests in your medical record. The investigator, ethics committee and government authorities can consult your medical records. Any public reports of the results of this study will not disclose your personal identity. We will try our utmost to protect the privacy of your personal medical information to the extent permitted by law.

In accordance with medical research ethics, research data will be available for public access and shared, except for private personal information, which will be limited to a web-based electronic database to ensure that no private personal information will be leaked.

**How to get more information?**

You can ask any question about this study at any time.

Your doctor will notify you promptly if there is any important new information during the study that may affect your willingness to continue to participate in the study.

**You can voluntarily choose to participate in the study and withdraw from the study in the middle**

Participation in the study is entirely at your discretion. You may refuse to participate in the study or withdraw from the study at any time during the study, and this will not affect the relationship between you and your physician, nor will it affect your medical treatment or any other loss of benefits.

For your best interest, your doctor or investigator may discontinue your participation in this study at any time during the study.

**What should I do now?**

It is up to you (and your family) to decide whether or not to participate in this study.

Before you make the decision to participate in the study, ask your doctor as many questions as possible about it.

Thank you for reading the above material. If you decide to participate in this study, please let your doctor know and he/she will make all the arrangements for you regarding the study. Please keep this material with you.

## Informed Consent Form - Consent Signature Page

**Project Title:** **Efficacy of Perioperative Intravenous Lidocaine Infusion on Postoperative Pulmonary Complications in Patients Undergoing Video-Assisted Thoracoscopic Lung Resection Surgery.**

**Subject unit:** **Sichuan Academy of Medical Sciences and Sichuan Provincial People's hospital**

**Subject Collaboration Unit:** **None**

**Statement of Consent**

I have read the above description of this study and have had opportunity to discuss and ask questions about this study with my doctor. All of the questions I asked were answered to my satisfaction.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary, I acknowledge that I have had sufficient time to consider it, and I understand that.

I can always ask my doctor for more information.

I may withdraw from this study at any time without discrimination or reprisal, and my medical treatment and rights will not be affected.

If I need to take any other medication due to a change in my condition, I will seek the doctor's advice beforehand or tell him/her truthfully afterwards.

I give permission for government administration, ethics committee or investigator representative to access my research data.

I will be given a signed and dated copy of the informed consent form.

Finally, I decided to agree to participate in this study and promised to follow the medical advice as much as possible.

Patient's signature: _____ Date: _____

Telephone: _____

Signature of legal representative (if applicable): _____

Date: _____ Telephone: _____

I confirm that I have been explained details of this trial to the patient including their rights and possible benefits and risks, and that they have been given a copy of the signed informed consent form.

Physician's signature: _____Date: _____

Telephone: _____