A Comparison of Energy Instruments and Stapling Devices to Dissect Intersegmental Planes in Segmentectomy: A Randomized Controlled Trial

Department of Thoracic Surgery

Ruijin Hospital Shanghai JiaoTong University School of Medicine

Registration Number: NCT03192904 (www.clinicaltrials.gov)

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Informed Consent Form

Introduction

We sincerely invite you to participate in a prospective, single-center randomized controlled clinical trial, which was initiated by Prof. Li Hecheng and named "A Comparison of Energy Instruments and Stapling Devices to Dissect Intersegmental Planes in Segmentectomy". This study was designed to investigate the short-term clinical efficacy and long-term survival of using energy instruments and stapling devices to dissect intersegmental planes during segmentectomy. It is essential to understand the purpose and content of the study before you decide to participate. Please read this introduction carefully and discuss it with your doctor, family and friends. If anything is unclear, or if you want to know more, please ask your doctor or contact the person listed after the introduction.

What is the purpose of the research?

Segmentectomy is one of the standard procedures for the treatment of GGO in the lung. The advantages and disadvantages of the methods for dissecting intersegmental planes are inconclusive. There are only a few retrospective case studies on short-term clinical efficacy and long-term survival. Our study selects the most commonly used approaches to dissect the intersegmental planes, tnergy instruments and stapling devices. It is hoped that this clinical trial will draw a conclusion of this problem.

Why were you selected?

We invite you to participate in the study, because you have found a ground glass opacity (GGO) in your physical examination and have indications for a segmentectomy. We will collect your perioperative outcomes, and long-term survival outcomes. After this trial, we hope to provide a reference for improving the prognosis of you and other patients.

Is this research risky?

If you agree to participate in the study, we need to collect your postoperative and post-discharge follow-up examination indicators and assessment data, without any adverse effects on your body, and it will not increase your risk except for routine medical care risk and unnecessary economy burden.

Need to pay?

You do not need to pay extra fees to participate in the study. But you will not receive any compensation for participating in this research. Your contribution to the medical profession is very meaningful.

Is my information confidential?

All information about you is kept strictly confidential during the research process. Only relevant personnel can view your medical records so that they can check the accuracy of the information collected and ensure that the research is conducted normally.

Any information transmitted electronically will be renamed to ensure the confidentiality of the information. The information on all computers will be protected with a password.
The results of the study may be reported at medical conferences and published in scientific journals. However, any information that identifies you personally will not be used.

Do I have to attend?
Participation in the study is entirely voluntary, not forced to participate. If you are participating in a study, you can opt out at any time without any reason. No matter what your decision is, it will not affect your normal treatment or your relationship with your healthcare provider.
If you decide to participate, we will ask you to sign an informed consent form. You will keep a copy of this consent form

Who conducts this trial?
This study is performed and completed by the Department of Thoracic Surgery, Shanghai Ruijin Hospital.

Who should I contact if I need more information?
After reading this introduction and discussing it with your doctor, if you have additional questions or concerns, please contact the following person:
Researcher: Dr. Xingshi Chen
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Who approved the study?
The study protocol and all amendments were reviewed and approved by the institutional review board of Ruijin Hospital Shanghai JiaoTong University School of Medicine (approval No. 2017-59).

I hereby agree to participate in the study.

Name: _____

Signature: _____ Date: _____

Witness Name：_____

Signature: _____ Date: _____