Informed Consent

Official title:

The Precise Surgical Treatment of Chronic Thromboembolic Pulmonary Hypertension: Pulmonary Endarterectomy Guided by Three-dimensional Pulmonary Angiography

Sponsor:Fuwai Hospital,Chinese Academy of Medical Sciences,Peking Union Medical College

Study types: interventional,Randomized single-blind controlled study

Document Date：12/19/2018

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Title： The Precise Surgical Treatment of Chronic Thromboembolic Pulmonary Hypertension: Pulmonary Endarterectomy Guided by Three-dimensional Pulmonary Angiography

Sponsor： Fuwai Hospital,Chinese Academy of Medical Sciences,Adult Cardiac Surgery Center

Institution：National Cardiovascular Center

What is the background and purpose of this study?

We invite you to participate in a randomized controlled trial of precision surgical treatment of chronic thromboembolic pulmonary hypertension.

Pulmonary endarterectomy is the first choice for the treatment of chronic thromboembolic pulmonary hypertension, which can improve the life quality significantly and prolong the life expectancy of these patients. The traditional treatment group guided the surgical exfoliation process with traditional diagnostic methods. The precise treatment group localized specific thrombus and intimal thickening places,a better stripping process might be achieved with the guide of precise three-dimensional pulmonary vascular imaging. The purpose of this study was to evaluate the efficiency of the precise treatment group and the effect of three-dimensional imaging technique for surgical treatment.

72 patients are expected to participate in the study. The independent ethics committee has approved this study.

What the procedures will I follow if I volunteer to participate in this study?

This study is a randomized controlled trial that may randomly assign you to either precise treatment group or the traditional treatment group. In the precise treatment group, we will accurately strip the pulmonary thickening intimal membrane and embolism based on accurate pulmonary CT and three-dimensional imaging. In the traditional treatment group, you will receive traditional standard pulmonary endarterectomy, in which the surgeon will perform adequate pulmonary endarterectomy without the guide of three-dimensional imaging techniques. In the process of randomization, there will be no additional burden on your diagnosis and treatment. Postoperative follow-up should be conducted in the specified time to determine your postoperative quality of life, pulmonary embolism recurrence and pulmonary pressure improvement.

What are the Possible risks and inconveniences in participating in the study?

This study is based on your consent. No matter which group you are assigned, you will receive standard pulmonary artery endarterectomy surgery.The main risk is surgery-related complications and risk of death. This study was conducted without any risk other than surgery.

What are your responsibilities in this research?

This study is a prospective study. When you participate in this study, you will agree to be followed up as required by the established study plan (generally 3 times in total, more frequent is better,generally 3 months, 6 months,12 months and 24 months after the operation), and agree that we will comprehensively observe and record your general situation, past medical history, pulmonary angiography results, ultrasound results, cardiopulmonary function results and other medical record.Any of your information will not be revealed to any other people except for the medical staffs in our co-ordination team of CTEPH.

What are the benefits of participating in the study?

Assigned to precise surgical treatment group will be able to get a free accurate three-dimensional imaging report, which will help the surgeon to accurately locate the embolism location and provide possible convenience for the surgery. During the study, the doctor will pay close attention to your physical condition and you will receive good medical care. We will guide your medication therapy and anticoagulation therapy at any time. The knowledge gained from this study may help other patients in the future.

Who should I contact for more information?

If you have any questions about this study, please contact doctor_____, phone number, _____; if you want to ask questions about your right, please contact: _____ Ethics Committee, Tel: _____.

How to handle the collected personal information?

Your information will be used for scientific research and the information will saved, but your name personal information such as your ID card number,will not be known throughout this study in order to protect your privacy. If the results of this study are published, your personal information will not be disclosed. The signing of this consent form indicates that you agree to share your medical information with us.

Members of the Ethics Committee and researchers of our coordination team will be allowed to have access to your relevant medical data,and can documented relevant parameters and data

according to your medical records;You and any staff in the Ethics Committee,can propose to monitor our use of the collected data from you,at any time,and you can choose to quit from this study at any time,this means the information we collected from you will not be allowed to be used for any other reason.

Agree to participate in the study

The researcher has fully explained the whole research process, potential risks and benefits to you. You also have ample opportunity to ask your own questions and get satisfactory answers.

You may refuse to participate in this study or withdraw from this study at any time. Your decision will not affect your medical services.

Your signature as a researcher (patient) indicates that you are aware of the above instructions and agree to participate in this study.

_____	_____	_____
Patient Name	Patient signature	Date
_____	_____	_____
Researcher Name	Researcher signature	Date