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A randomized clinical trial to assess the postoperative pulmonary function and quality of life of preservation of the pulmonary ligament versus division of the pulmonary ligament for patients undergoing video-assisted thoracic surgery upper lobectomy

Submission date	**Recruitment status**	[X] Prospectively registered
01/11/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/11/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/04/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
NSCLC (non-small cell lung cancer) describes different types of lung cancer. There is no convincing evidence that dissection(removal) of the pulmonary ligament (part of the lung) in an upper lobectomy (a type of surgery where one lobe of the lung is removed) significantly improves outcomes and reduces complications than leaving it intact. This study uses video-assisted thoracic surgery to help with the procedure. This study was designed to testify whether preservation of the pulmonary ligament can provide better pulmonary function and quality of life when compared with division this ligament for patients undergoing video-assisted thoracic surgery upper lobectomy.

Who can participate?
Adults aged 18-80 years old who have never underwent thoracic surgery before diagnosed with upper lobe (NSCLC).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their pulmonary ligament preserved. Those in the second group have the inferior pulmonary ligament divided during video-assisted thoracic surgery upper lobectomy. In the preservation of the pulmonary ligament (PPL) group, patients are allocated to receive video-assisted thoracic surgery (VATS) upper lobectomy which preserving the pulmonary ligament. In the division of the pulmonary ligament (DPL) group, patients are allocated to receive video-assisted thoracic surgery (VATS) upper lobectomy which divides the pulmonary ligament. Postoperative pulmonary function test and quality of life scale are assessed three to six months after the operation.

What are the possible benefits and risks of participating?
Participants may benefit from better pulmonary function and quality of life. The possible risk is that the treatment may fail promote pulmonary function when compare with division of the pulmonary ligament (DPL) group.

Where is the study run from?
Second Affiliated Hospital of Zhejiang University (China)

When is the study starting and how long is it expected to run for?
November 2017 to May 2019

Who is funding the study?
Second Affiliated Hospital of Zhejiang University School of Medicine (China)

Who is the main contact?
Professor Ming Wu

Contact information

Type(s)
Scientific

Contact name
Prof Ming Wu

Contact details
Department of Thoracic Surgery
The Second Affiliated Hospital of Zhejiang University
Hangzhou
China
310000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Preservation of the pulmonary ligament during video-assisted thoracic surgery upper lobectomy provide less pulmonary function damage and better quality of life for patients after operation than division of the pulmonary ligament

Study objectives
The aim of this study is examine whether preservation of the pulmonary ligament can provide better pulmonary function and quality of life when compared with division this ligament for patients undergoing video-assisted thoracic surgery upper lobectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Second Affiliated Hospital of Zhejiang University, 23/10/2017

Study design
Single-center randomised study conduct to compare preservation of the pulmonary ligament with division of the pulmonary ligament about postoperative pulmonary function and quality of life for patients undergoing video-assisted thoracic surgery upper lobectomy.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Postoperative pulmonary function and quality of life of non-small cell lung cancer (NSCLC) patients who undergoing video-assisted thoracic surgery (VATS) upper lobectomy will performed 3 months to 6 months after operation

Interventions
Participants are randomly allocated to one of two groups.

In the preservation of the pulmonary ligament (PPL) group, patients are allocated to receive video-assisted thoracic surgery (VATS) upper lobectomy which preserving the pulmonary ligament.

In the division of the pulmonary ligament (DPL) group, patients are allocated to receive video-assisted thoracic surgery (VATS) upper lobectomy which dividing the pulmonary ligament.

Postoperative pulmonary function and quality of life of patients is assessed three to six months after operation for both groups.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Postoperative pulmonary function is measured using the variation of indicators in pulmonary function test between preoperation and postoperation at three to six months after the operation
2. Quality of life is measured using two standard questionnaires: the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ–C30) and its lung cancer supplementary questionnaire (QLQ–LC13) at three to six months after the operation

Secondary outcome measures
1. Complications after surgery is measured using patient notes after surgery and before discharge
2. Chest tube duration(whether thoracocentesis) is measured using patient notes after surgery and before discharge
3. The number of patients who are capable of a good cough is measured using patient notes on postoperative days one, two and three
4. Total hospital stay is measured using patient notes on discharge
5. Time in the ICU is measured using patient notes on discharge
6. Mortality within 30 days after surgery

Overall study start date
01/11/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Patients who never have underwent thoracic surgery and chemotherapy before diagnosed with upper lobe non-small cell lung cancer (NSCLC) are deemed suitable for single intercostal video assisted thoracic surgery.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
about 60 patients in each group

Key exclusion criteria
1. Unresectable tumors
2. Older than 80-years-old
3. Deemed suitable for chemotherapy after surgery

Date of first enrolment

30/11/2017

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
China

Study participating centre
Second Affiliated Hospital of Zhejiang University
The Thoracic Surgery Department
Hangzhou
China
310000

Sponsor information

Organisation
The Thoracic Surgery of the Second Affiliated Hospital of Zhejiang University

Sponsor details
No. 88 Jiefang road
Zhejiang Province
Hangzhou
China
310000

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/059cjpv64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Second Affiliated Hospital of Zhejiang University School of Medicine (China)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and intent to publish date around one year after our overall trial end date.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Shuai Fang at 964730338@qq.com.

IPD sharing plan summary
Available on request