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# New dual-tube technique to manage air leaks after lung surgery

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| **Submission date**<br>01/07/2024 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>03/07/2024 | **Overall study status**<br>Completed | |
| **Last Edited**<br>02/07/2024 | **Condition category**<br>Surgery | |

## Plain English summary of protocol

Background and study aims
Researchers are conducting a study at Zhongda Hospital, affiliated with Southeast University, to improve how they manage air leaks that occur after lung surgery, a common issue that can prolong hospital stays and increase complications. Traditionally, a method called autologous blood patch pleurodesis (ABPP) is used that uses a patient's own blood to seal these leaks. A new method involves two chest tubes and utilizes naturally occurring blood within the chest to seal the air leaks more effectively. This study aims to see if this new double chest tube method can shorten recovery times and reduce complications more than the traditional single-tube method.

Who can participate?
Adults aged 18 years and above diagnosed with non-small cell lung cancer, who are scheduled for lung lobectomy through a minimally invasive technique called Uniportal Video-Assisted Thoracoscopic Surgery (U-VATS)

What does the study involve?
Participants will be randomly assigned to one of two groups: one receiving the new double tube treatment and the other receiving the traditional single tube treatment. The treatment effectiveness will be monitored from the day of surgery until discharge, about 1-2 weeks.

What are the possible benefits and risks of participating?
While there is no direct benefit to participants, the study may help identify more effective treatment methods for future patients. The risks are associated with typical complications of chest tubes used in lung surgeries, such as pain, infection, or air and blood accumulation in the chest, which will be closely monitored.

Where is the study run from?
Zhongda Hospital, Southeast University (China)

When Is the study starting and how long is it expected to run for?
July 2018 to December 2021

Who Is funding the study?
Zhongda Hospital, Southeast University (China)

Who is the main contact?
Dr Li Hongyan (Deputy Chief Physician at Zhongda Hospital), drlihongyan@sina.com. The contact details are also available through the Hospital's Ethics Committee at +86 (0)25-83272015.

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
2018ZDKYSB101

# Study information

### Scientific Title
Evaluating the effectiveness of double chest tube management utilizing naturally occurring pleural blood for managing prolonged air leaks after uniportal video-assisted thoracoscopic surgery lobectomy: a single-center randomized controlled trial

### Acronym
DCTM-PAL

### Study objectives
Autologous blood patch pleurodesis (ABPP) utilizes the patient's own blood to effectively seal leaks. Building on the principles of ABPP, this study introduces a novel double chest tube

management technique utilizing naturally occurring pleural blood post-uniportal video-assisted thoracoscopic surgery (U-VATS) lobectomy. It is hypothesized that this method may harness the natural healing properties of pleural blood, serving as a biological sealant for air leaks.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 28/11/2018, IEC for Clinical Research of Zhongda Hospital, Affiliated to Southeast University (87 Dingjiaqiao Gulou District Nanjing, Nanjing, 210009, China; +86 (0)25 8327 2015; zdyyrsk@163.com), ref: 2018ZDKYSB101

## Study design
Single-center randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital, Medical and other records

## Study type(s)
Treatment, Safety, Efficacy

## Participant information sheet
See study outputs table

## Health condition(s) or problem(s) studied
Treatment for postoperative air leakage in patients undergoing U-VAT pulmonary lobectomy

## Interventions
The intervention involves a double chest tube strategy for managing post-surgical pleural blood: a 20F chest drainage tube without extra holes and a 19F round type of flexible silicone tube equipped with grooves that run along the tube length. The 20F chest tube, positioned anteriorly in the apex of the pleural cavity, was dedicated to continuous air removal and connected to a water-sealed drainage bottle. The 19F soft tube was placed over the diaphragm and connected to a suction ball to allow intermittent drainage of the naturally occurring blood in the pleural cavity post-surgery.

Participants will be randomly assigned to one of two groups: one receiving the new double tube treatment and the other receiving the traditional single tube treatment. The treatment effectiveness will be monitored from the day of surgery until discharge, approximately 1-2 weeks.

The randomization occurs intraoperatively after the completion of the resection and hemostasis. A member of the surgical team will employ a simple random sampling technique to assign

eligible patients to either the control group (with a single chest tube) or the study group (with double tubes). This will be facilitated using SAS statistical software (SAS Institute, Cary, NC, USA), ensuring a randomized allocation of patients in a 1:1 ratio between the two groups.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Time to chest tube removal in full days following lobectomy. The criteria for removing chest tube included: (1) the drainage volume less than 200 ml over the preceding 24 h; (2) absence of intrathoracic hemorrhage or air leakage, and (3) no signs of pleural effusion or atelectasis.

### Secondary outcome measures
1. The incidence of prolonged postoperative air leakage measured using monitoring by daily observation of the water seal chamber.
2. The total cumulative volume of chest drainage measured using daily counting the records of the chest chamber.
3. The postoperative hospital stay measured by counting at the time of discharge from hospital.
4. The incidence of postoperative complications and mortality measured by counting the records of the electronic hospital charts at the time of discharge from hospital.

### Overall study start date
01/07/2018

### Completion date
31/12/2021

## Eligibility

### Key inclusion criteria
1. Preoperative assessment or intraoperative frozen section confirming non-small cell lung cancer (NSCLC)
2. A clinical diagnosis of stage I to IIIA disease, as classified by the 8th edition of the TNM classification for lung cancer
3. Age between 18 and 75 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
75 Years

### Sex
Both

### Target number of participants
50

### Total final enrolment
96

### Key exclusion criteria
1. Preoperative complications such as atelectasis, pulmonary infection, or tuberculosis
2. Presence of hemothorax or empyema
3. History of a previous lobectomy
4. Significant dense pleural adhesions
5. Tumors that had invaded the chest wall (T3 classification)
6. Requirement for a bilateral lobectomy

### Date of first enrolment
01/01/2019

### Date of final enrolment
31/12/2021

## Locations

### Countries of recruitment
China

### Study participating centre
**Zhongda Hospital Southeast University**
87 Dingjiaqiao Gulou District
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## Sponsor information

### Organisation
Zhongda Hospital Southeast University

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### Sponsor type
Hospital/treatment centre

### Website
http://www.njzdyy.com/

### ROR
https://ror.org/01k3hq685

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Zhongda Hospital Southeast University

## Results and Publications

### Publication and dissemination plan
Planned publication in a peer-reviewed journal

### Intention to publish date
01/08/2024

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Li Hongyan (drlihongyan@sina.com). The individual participant data underlying the results reported in this study will be shared from six months to three years following an article publication. Consent for data sharing was obtained from participants as mentioned in the consent forms. Data are fully anonymized, removing all personal identifiers. Any sharing will be per ethical approvals and subject to data-sharing agreements.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 2.0 | 13/10/2018 | 02/07/2024 | No | Yes |
| Protocol file | version 2.0 | 13/10/2018 | 02/07/2024 | No | No |