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

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

Contact name
Dr Hongyan Li

Contact details
87 Dingjiaqiao Gulou District
Nanjing
China
210009
+86 (0)13645188806
drlihongyan@sina.com

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single-center randomized controlled trial

Study type(s)
Treatment, Safety, Efficacy

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

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
Nanjing
China
210009

Sponsor information

Organisation
Zhongda Hospital Southeast University

ROR
https://ror.org/01k3hq685

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Zhongda Hospital Southeast University

Results and Publications

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