ISRCTN15099654 https://doi.org/10.1186/ISRCTN15099654

A study testing different treatments to help stop air leaks from collapsed lung

Submission date
08/07/2025

Recruitment status
Recruiting

Registration date
24/07/2025

Overall study status
Ongoing

Last Edited
15/12/2025

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sometimes, air can get stuck between the lung and chest wall, causing the lung to collapse. This is called a pneumothorax. When this happens to people who already have lung problems, it's called "secondary spontaneous pneumothorax" (SSP). Normally, doctors treat this problem by putting a drain in your chest to help remove the air. The drain can stay for about a week or longer.
Sometimes, the air keeps leaking for more than 2 days. This is called a "persistent air leak" (PAL), and we don't always know the best way to treat it. Right now, doctors often wait to see if the air leak stops on its own, which can take a while—sometimes even weeks.
There are a few other treatments doctors use, but we don't know which one works best or which order they should be given. This is a feasibility study that will help us to work out whether it is possible to design and conduct a larger study that will answer those question.

Who can participate?
Patients with either a lung disease or over 50 years old with a history of smoking, who are in hospital because they have a problem where air is trapped between their lung and chest wall, causing their lung to collapse, and the lung is still leaking air after 2 days.

What does the study involve?
In the study, half of the participants will initially get treatment using SUCTION to help remove air, and the other half will get the USUAL CARE without suction. If the air leak still doesn't stop after 3 more days, the participant will be given one of three different treatments:
Endobronchial Valves: Special valves are put inside your lung to block the air leak. This is done with a thin tube that goes into your mouth.
Autologous Blood Patch: Doctors take a little of your blood from your arm and put it into your chest to help stop the air leak.
Usual Care: This means just waiting for the lung to heal on its own.
If the air leak hasn't stopped 10 days after the participant started the study, the doctor may decide to try one of the other treatment options.
Participants will be asked to complete two short questionnaires after you have provided your consent, on day 7 of the study and at your day 90 visit.

What are the possible benefits and risks of participating?
There may not be any direct benefits for each participant. But the study will help doctors learn more about how to treat people with this lung problem, which can help future patients.
All trial treatments, suction, endobronchial valves, autologous blood patch, as well as no additional treatments are all standard treatments that are used in the NHS. They all have some evidence to support their use, however none of the evidence is strong enough to make strong recommendations that they should be used for every patient with SSP.

Where is the study run from?
The study is being organised and run by Bristol Academic Respiratory Unit on behalf of North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in September 2025 and the study will recruit over 24 months. Once enrolled in the study, a participant will be involved for 90 days.

Who is funding the study?
This study is funded by the National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Steven Walker, steven.walker@bristol.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Steven Walker

Contact details
Academic Respiratory Unit,
University of Bristol
Level 2, Learning and Research Building,
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 117 414 8114
steven.walker@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
348034

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 65614, NIHR303204

Study information

Scientific Title
Platform Randomised feasibility trial Of Suction, Endobronchial valves and Autologous blood patch on air-Leak

Acronym
PRO-SEAL

Study objectives
To test whether is it feasible and acceptable to conduct a multi-center randomised platform trial to evaluate the use of interventions for persistent air leak in patients with pneumothorax secondary to underlying lung disease

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/07/2025, London - Central Research Ethics Committee (3rd Floor, 3 Piccadilly Place, London Road, Manchester, M1 3BN, United Kingdom; +44 207 104 8061; londoncentral.rec@hra.nhs.uk), ref: 25/LO/0483

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Persistent air-leak

Interventions
Autologous blood patch (ABP), Patients randomised to ABP will have 1mg/kg of blood aspirated by appropriately trained clinician. This blood will be then instilled via the drain into the pleural space.
Endobronchial valve (EBV), Participants assigned Endobronchial valve (EBVs) will be referred for EBV placements. This will inserted via bronchoscopy. This can be performed under conscious sedation or general anaesthetic (GA), depending on local protocols. This will be done by an appropriately trained clinician.
Thoracic suction , Patients randomised to Thoracic suction will have suction applied to their

chest drainage system by a staff nurse. The suction would continue as long as drain remains in place.
Follow up for 90 days.

Eligible patients will be randomised (1:1:1:1:1:1) through a randomisation server. A member of the trial team will randomise patients as soon as eligibility has been confirmed and consent obtained. Randomisation will use a commercial secure, internet-based system, Sealed Envelope. A minimisation algorithm with random element will be implemented, balancing on underlying lung disease (COPD/non-COPD) and recruiting site.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The proportion of the total number of patients who are eligible for trial entry who accept randomisation measured using patient records at end of study

Key secondary outcome(s))
Measured using patient records (unless noted otherwise):
1. Duration of air-leak in first 90 days
2. Duration of chest drain in-situ in first 90 days
3. Proportion of patients with air-leak cessation 72hours after 2nd intervention
4. Proportion of patients meeting inclusion and exclusion criteria approached by trial team
5. Proportion of patients randomised who receive the first allocated intervention
6. Proportion of patients randomised who receive the second allocated intervention
7. Proportion of patients randomised who complete trial follow-up
8. Pain (using visual analogue score, VAS) and breathlessness (VAS) measured post-intervention, day 7 and at day 90 post-randomisation (±7 days)
9. Patient-reported health status (EQ-5D-5L) measured post-intervention (within 24 hours), day 5 and day 90 post-randomisation (±14 days)
10. To assess patient views and experiences of interventions and study design
11. To assess clinician views of interventions and study design
12. Total number of pleural procedures in first 90 days
13. Length of initial hospital stay (LOHS) in first 90 days
14. Surgical referral and acceptance rates in first 90 days
15. Mortality rates in first 90 days
16. Serious adverse rates in first 90 days

Completion date
25/08/2028

Eligibility

Key inclusion criteria
1. A secondary spontaneous pneumothorax, defined as a pneumothorax occurring in a patient with known underlying or suspected lung disease or >50 years of age with a smoking history
2. Ongoing air-leak ≥48hours after insertion of intercostal drain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. They have bilateral pneumothoraces
2. They have a traumatic or iatrogenic pneumothorax
3. They are < 18 years of age
4. Inmate of the prison systems of England and Wales, Scotland or Northern Ireland
5. Patient lacking capacity to consent for themselves

Date of first enrolment
15/12/2025

Date of final enrolment
22/09/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Manchester University NHS Foundation Trust
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
St Georges Hospital
Blackshaw Road
London
England
SW17 0QT

Study participating centre

University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository, the University of Bristol's data repository, data.bris, where the dataset will be issued a DOI, which will then be cited in the body of the research publication.

Data will only be available for 5 years after the trial has concluded and after publication of the main study results. No identifiable data will be shared, it will be fully anonymised. Data sharing will be in line with the University of Bristol's Open Research policy. Anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the University of Bristol's Open Research policy regarding information security, information governance, ethical requirements, and a data access agreement has been signed by their institution.

IPD sharing plan summary

Stored in publicly available repository