A trial of suction for the early resolution of a collapsed lung

Submission date	Recruitment status Recruiting	[X] Prospectively registered		
24/11/2022		☐ Protocol		
Registration date 07/12/2022 Last Edited 23/05/2025	Overall study status Ongoing Condition category Respiratory	Statistical analysis plan		
		Results		
		Individual participant data		
		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

A pneumothorax occurs when air gets into the space between the lung and the chest wall, usually through a small hole in the lung. This causes the lung to collapse and can occur "spontaneously", meaning without an injury to the chest. Primary spontaneous pneumothorax (PSP) occurs in younger patients without known lung disease. Most patients with PSP need to have a tube (or drain) inserted into the chest to remove the air between the lung and chest wall. This allows the lung to re-inflate. The tube is attached to a bottle with water in it, creating an underwater seal, and air bubbles out through the water.

Although some patients with PSP can be treated at home (either by not draining the chest or with a home drainage device), at least 50% of patients stay in the hospital waiting for the lung to re-inflate for 4 to 8 days. In these patients, it is possible to provide suction (negative pressure) to the drain with the aim of expanding the lung more quickly and reducing time in the hospital. However, we do not know if using suction is helpful, or if it has risks. There have been no large studies conducted to prove whether suction is effective in reducing treatment time. The current guidelines provide conflicting advice on the routine use of suction, but despite this, doctors often use it. We want to address this question directly. Reducing treatment time is important because interviews and questionnaires conducted with patients who have had a pneumothorax have told us that their top priorities include reducing the amount of time that they have a chest tube and the length of their hospital stay. In addition, treating these patients in hospital costs the NHS around £7.2m per year, so safely reducing the time spent in the hospital will be cost-saving for the NHS.

Who can participate?

Patients aged 16* to 50 years old with PSP being treated at 36 centres in hospitals around the UK. *Common law presumes that young people aged between 16 and 18 years old are usually competent to give consent to treatment and consent from those with parental responsibility is not legally necessary. Eligible young persons believed to be competent by the PI or delegate should be approached about the study. The involvement of parents in decision-making should be encouraged unless the young person objects.

What does the study involve?

Patients will be randomly assigned to either have suction applied to their chest tube or treated with usual care (no suction) and followed up for 6 months in total.

What are the possible benefits and risks of participating?

In terms of benefits, those randomly assigned to suction may resolve their pneumothorax more quickly and hence a shorter hospital stay. When the study is complete, we hope the information collected will help to improve the treatment of patients in the future. Once admitted to the hospital with a chest drain, management of ongoing pneumothorax remains contentious. The rationale behind the use of suction (the application of negative pressure to the pleural space via the chest tube) is that the lung will expand more quickly and potentially heal more quickly once the lung is re-expanded and in contact with the parietal pleura. However, suction is not without risk, as it may precipitate injury to the lung (by too rapidly expanding the lung, or may result in delayed healing of the pneumothorax if the application of suction maintains flow through the hole in the lung. Patients will have daily chest x-rays (CXRs) during their admission as per standard care. There are theoretical health risks from excessive radiation exposure, but CXRs are the safest tests (the radiation dose is only equivalent to around four days' worth of normal background radiation). No additional radiological investigations will be undertaken for research purposes. All patients will be carefully monitored for safety outcomes in both arms of the trial, with adverse events reported and reviewed according to the Oxford Respiratory Trials Units (ORTU) standard operating procedures.

Where is the study run from? Oxford Respiratory Trials Unit, University of Oxford (UK)

When is the study starting and how long is it expected to run for? May 2022 to February 2027

Who is funding the study? National Institute for Health and Care Research - Health Technology Assessment (NIHR-HTA) (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 54383, IRAS 316434

Study information

Scientific Title

Randomised trial of suction for primary pneumothorax early resolution

Acronym

RASPER

Study objectives

It is hypothesised that using suction to treat people in the hospital with a lung collapse is safe and can shorten the time that people need to have a chest tube in place.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/11/2022, West Midlands, Solihull (Meeting held by video-conference via Zoom; +44 (0)207 104 8191, (0)207 104 8269; solihull.rec@hra.nhs.uk) ref: 22/WM/0253

Study design

Multi-centre open-label randomized controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary spontaneous pneumothorax

Interventions

RASPER is a multi-centre open-label randomised controlled trial of patients with primary spontaneous pneumothorax (PSP) requiring treatment in the hospital. The aim of the study is to assess the superiority of suction versus standard care with respect to total treatment duration. The main hypothesis is that treatment duration will be significantly reduced by the use of suction, as compared to standard care. Suction devices are currently in clinical use in the UK but are used inconsistently without any clear evidence of benefit. The use of suction has not been robustly tested in a large clinical trial, compared to standard management, as we propose here. 450 patients with PSP requiring chest drainage in the hospital will be enrolled from 36 UK centres, including our established pneumothorax network. Patients will be screened from respiratory and general medical wards. Data will be collected from routinely recorded clinical

data and patient-completed questions on pain and breathlessness scores and overall health (EQ5D). Other important factors being assessed include safety, the level of comfort of the device, and the cost-effectiveness of the use of suction.

Patients requiring treatment in a hospital with a chest drain in place (to re-inflate the lung) will be invited to take part in the randomised control trial: and randomly assigned to one of two groups: suction arm or standard care (no suction).

Baseline.

At baseline patients will have a chest-x ray or CT (rarely) to confirm their diagnosis. As part of the study, patients will have their demographics/medical history taken, they will be asked to complete a questionnaire (EQ-5D-5L) and another one about pain and breathlessness (VAS assessment).

1. Intervention arm: Suction

The suction will be incrementally increased as per a trial-specific procedure: starting at -1.0kPa (-10cm H20, -7.5mmHg), increasing to -1.5kPa and then -2.0kPa as tolerated, every 2-4 hours). Suction should be reduced on the basis of specific criteria (pain, complications). Adherence will be documented on daily clinical review CRFs.

2. Control arm: Usual care

Patients in the usual care will be managed as standard (as per current national guidelines) without the use of suction (i.e. connected to an underwater seal bottle) unless suction is clinically needed for safety reasons. For example, rarely the air leak from the lung is too large to be drained by the chest drain and the pneumothorax continues to get larger despite the drain working – in this situation suction will be allowed for safety reasons (and recorded in the trial records).

Follow-up

Patients will be followed up 14 days (+/- 3 days) in person after completion of treatment, at 30 days (+ up to 7 days) in person/over the phone and 6 months (+/- 2 weeks) after enrolment by telephone. Patients will be asked to complete an online questionnaire, about pain and breathlessness, and tell us if they had any contact with healthcare providers since their last visit (for health economic analysis).

Minimising Bias

Due to the nature of the interventions, patients and clinicians cannot be blinded to allocation and therefore code-breaking is not needed for this trial. However, criteria will be specified for "chest drain removal" and "surgical referral/failure of medical treatment" to provide objective data that will be blind reviewed after the trial by an independent assessor blind to the treatment arm (i.e. objective blind outcome assessment) and compared to actual treatment duration at study end.

Interim Monitoring and Analyses

A blinded interim analysis of the primary outcome (hospital stay) will be undertaken after approximately 50% of patients have been recruited in order to assess the assumptions made in the sample size calculation. This analysis will be reviewed by the DSMC which will make recommendations regarding any necessary changes to the sample size required. No correction of the significance level of the final analysis is planned on this single assessment of the early event rate by the DSMC.

Patient and public involvement

We conducted a survey of twelve patients to find out what was most important to them and designed this trial based on the results. The survey showed that patients that their top priorities are: 1. To reduce the amount of time that they have a chest tube, and 2. To reduce the length of their hospital stay. A representative from our patient group who previously had a PSP has reviewed the patient-facing documents (including the patient information sheet) and is a member of the trial committee and will represent our Patient Advisory Group.

Procedure/Surgery

Primary outcome(s)

Total treatment duration, defined as the time from randomisation to completion of pleural treatment (including surgery, if required), measured using data recorded in patient medical notes at the completion of treatment (discharge home from hospital with no drain in place)

Key secondary outcome(s))

Outcomes measured using data recorded in patient medical notes:

- 1.1. In-patient surgical rates at the completion of treatment
- 1.2. Length of hospital stay over first the 30 days post-randomisation (including readmissions) at 30 days post-randomisation
- 1.3. Pain and breathless scores (100mm Visual Analogue Scale (VAS)) at baseline, daily until completion of treatment, and at follow-14 days after the completion of treatment and 30 days post-randomisation)
- 1.4. EQ5D at baseline, Completion of treatment, 30 days and 6 months post-randomisation
- 1.5. Rate of recurrence of pneumothorax at 6 months post-randomisation
- 2. Incremental cost per quality-adjusted life years (QALYs) gained at randomisation to 6 months measured using data gathered between those timepoints
- 3.1. Complication rates at the completion of treatment
- 3.2. Overall number of in-patient pleural procedures at the completion of treatment
- 3.3. Adverse events related to the use of suction at the completion of treatment

Completion date

27/02/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 21/05/2025:

- 1. Participants with primary spontaneous pneumothorax (PSP) (either first or recurrent episode)
- 2. Male and Female aged 16* to 50 years old OR aged 51 to 60 years old without significant smoking history
- 3. Pneumothorax requiring chest drain in hospital (ideally within 24 hours of drain insertion, but up to 72 hours))
- 4. Willing and able to give written consent
- 5. Access to an electronic device for questionnaire completion

*Common law presumes that young people aged between 16 and 18 years old are usually competent to give consent to treatment and consent from those with parental responsibility is not legally necessary. Eligible young persons believed to be competent by the PI or delegate should be approached about the study. The involvement of parents in decision-making should be encouraged unless the young person objects.

Previous inclusion criteria:

- 1. Participants with primary spontaneous pneumothorax (PSP) (either first or recurrent episode)
- 2. Male and Female aged 16* to 50 years old
- 3. Pneumothorax requiring chest drain in hospital (ideally within 24 hours of drain insertion, but up to 72 hours))
- 4. Willing and able to give written consent
- 5. Access to an electronic device for questionnaire completion

*Common law presumes that young people aged between 16 and 18 years old are usually competent to give consent to treatment and consent from those with parental responsibility is not legally necessary. Eligible young persons believed to be competent by the PI or delegate should be approached about the study. The involvement of parents in decision-making should be encouraged unless the young person objects.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Upper age limit

60 years

Sex

All

Key exclusion criteria

- 1. Known or suspected underlying lung disease**. This does not include the presence of blebs /bullae on CT chest in the absence of another specific respiratory diagnosis
- 2. Inability to consent or comply with trial requirements
- 3. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the trial, or the participant's ability to participate in the study.

**"Childhood asthma" is not considered an exclusion criterion. Patients with a diagnosis of asthma in childhood/young adulthood who do not require the use of a regular "preventer" inhaler (i.e. inhaler containing a steroid or long-acting beta-agonist), and only occasionally use a "reliever" inhaler (short-acting beta-agonist) and have never been hospitalised due to asthma remain eligible for participation in this study.

Date of first enrolment

27/02/2023

Date of final enrolment

27/02/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Addenbrookes

Addenbrookes Hospital Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre John Radcliffe Hospital

Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Plymouth Hospital

Derriford Hospital Derriford Road Plymouth United Kingdom PL6 8DH

Study participating centre Imperial College Healthcare NHS Trust

The Bays St Marys Hospital South Wharf Road London United Kingdom W2 1BL

Study participating centre

St Thomas' Hospital

Westminster Bridge Road London United Kingdom SE1 7EH

Study participating centre The Royal Victoria Infirmary

Queen Victoria Road Newcastle upon Tyne United Kingdom TS1 4LP

Study participating centre Furness Hospitals NHS Trust

Furness General Hospital Dalton Lane Barrow-in-furness United Kingdom LA14 4LF

Study participating centre Princess Royal University Hospital

Farnborough Common Orpington United Kingdom BR6 8ND

Study participating centre Norfolk & Norwich University Hospital

Colney Lane Colney Norwich United Kingdom NR4 7UY

Study participating centre Royal Stoke University Hospital

Newcastle Road

Stoke-on-trent United Kingdom ST4 6QG

Study participating centre City Hospital NHS Trust

City Hospital N H S Trust Dudley Road Birmingham United Kingdom B18 7QH

Study participating centre Queen Elizabeth Hospital

Queen Elizabeth Medical Centre Edgbaston Birmingham United Kingdom B15 2TH

Study participating centre Watford General Hospital

60 Vicarage Road Watford United Kingdom WD18 0HB

Study participating centre Aneurin Bevan University Lhb

Headquarters - St Cadoc's Hospital Lodge Road Caerleon Newport United Kingdom NP18 3XQ

Study participating centre Northern General Hospital

Northern General Hospital NHS Trust C Floor, Huntsmnan Building Herries Road Sheffield United Kingdom S5 7AU

Study participating centre

Chelsea and Westminster Hospital NHS Foundation Trust

Chelsea & Westminster Hospital 369 Fulham Road London United Kingdom SW10 9NH

Study participating centre Macclesfield District General Hospital

Macclesfield District Hospital Victoria Road Macclesfield United Kingdom SK10 3BL

Study participating centre Royal Lancaster Infirmary

Ashton Road Lancaster United Kingdom LA1 4RP

Study participating centre

St James's University Hospital NHS Trust

St James's University Hospital Gledow Wing Beckett Street Leeds United Kingdom LS9 7TF

Study participating centre Pinderfields General Hospital

Aberford Road

Wakefield United Kingdom WF1 4DG

Study participating centre Queen Elizabeth Hospital

Woolwich Stadium Road Woolwich London United Kingdom SE18 4QH

Study participating centre West Suffolk Hospital

Hardwick Lane Bury St. Edmunds United Kingdom IP33 2QZ

Study participating centre The Worcestershire Royal Hospital

Newtown Road Worcester United Kingdom WR5 1ZL

Study participating centre Glenfield General Hospital

Groby Road Leicester United Kingdom LE3 9QP

Study participating centre Chesterfield Royal Hospital NHS Foundation Trust

Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre Queen Elizabeth University Hospital

1345 Govan Road Glasgow United Kingdom G51 4TF

Study participating centre Arrowe Park Hospital (site)

Arrowe Park Hospital
Arrowe Park Road
Wirral
United Kingdom
CH49 5PE

Sponsor information

Organisation

University of Oxford

ROR

https://ror.org/052gg0110

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

LocationUnited Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Individual participant data will be available for sharing after de-identification to researchers who provide a methodologically sound proposal. The study protocol, consent forms, and participant information leaflet will also be available on request immediately after publication. Data may be shared to allow researchers to achieve the aims of their approved proposal. There is no planned end date for data sharing. Data requests should be submitted to ORTU@ndm.ox.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes