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

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

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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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

316434

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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.

Intervention Type
Procedure/Surgery

Primary outcome measure
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)

Secondary outcome measures
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

Overall study start date
31/05/2022

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.

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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

Age group
Adult

Lower age limit
16 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
Planned Sample Size: 450; UK Sample Size: 450

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
England

United Kingdom

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

Sponsor details
Research Governance, Ethics and Assurance
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Churchill Drive
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Telephone number not available
rgea.sponsor@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/11/2027

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