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Treating people with a lung collapse (pneumothorax) without inserting a needle into the chest. Is it safe and effective?

Submission date
21/12/2022

Recruitment status
Recruiting

Registration date
31/01/2023

Overall study status
Ongoing

Last Edited
03/07/2025

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
Primary spontaneous pneumothorax (PSP) is an abnormal collection of air in the space between the lung and the chest wall, causing the lung to collapse. This type of pneumothorax is called primary, as it happens in patients with no underlying lung disease, and spontaneous, as it occurs without injury. Previous work by our group shows that 3,000 patients a year need admission to a hospital to treat a PSP. Currently, patients with symptoms are treated by draining the air through a needle or tube put into the chest, as it is thought to reduce symptoms of pain and breathlessness and speed recovery. This treatment means patients often stay in the hospital for one week and puts patients at risk of complications from the treatment (for example, infection).

Patients whose lung has only partially collapsed (small PSP) or who have fewer symptoms can be managed “conservatively”, this means not draining the air, and being observed instead. However, it is not clear whether it is safe to do this in patients with symptoms and a larger collapse (large PSP). Research published in 2020 from Australasia compared draining the air with observation only in patients with large symptomatic PSP. The researchers found that observation was as good as draining the air but there were problems with the research and, although these results are promising, they have not changed how doctors treat patients.

The CONSEPT trial will investigate whether observation only in patients with a large symptomatic PSP is safe and effective with respect to outcomes that are important to patients, such as the need for invasive treatments and length of hospital stay.

Who can participate?
Patients with PSP aged between 16 and 50 years old

What does the study involve?
Participants will be put into one of two groups by chance. The observation-only group will not have the air drained but will be monitored for a few hours, and if comfortable and stable, discharged from the hospital. The second group will be treated in the usual way by draining the air through a needle or tube. We will collect information to see if patients need to have a

subsequent drainage in the first month after having the PSP, and measure symptoms and general health. We will also monitor whether the PSP recurs within a year.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part as the research team does not know which treatment is better, however, the information generated by this study may help improve the treatment of people with PSP in the future. The current standard care for PSP is to perform an invasive treatment. This might help people to get better more quickly, but all of these treatments have small risks associated with them, for example, infection. The conservative treatment arm may mean the patient avoids an invasive treatment, but as a result, the pneumothorax might take longer to improve, or the patient might need an invasive treatment further down the line. It also risks the pneumothorax getting worse when the patient is at home having not had the PSP drained. This will be closely monitored throughout the study and the clinical team will ensure the patient is followed up regularly. Patients will have a number of chest X-rays when taking part in the study, one of which may be in addition to those already schedule if not taking part. Chest X-rays use ionising radiation to form images of the body and to provide the doctor with other clinical information. The risk of radiation exposure is that patients may develop cancer some years in the future. Everyone is at risk of developing cancer during their lifetime. The normal risk is that this will happen to about 1 in 2 people at some point in their life. The additional risk from the extra X-ray that may be received as part of the study is very small and is outweighed by the benefit of the information the X-ray provides.

Where is the study run from?
Bristol Trials Centre at the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
November 2021 to February 2027

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

Who is the main contact?
Lucy Hamilton (Trial Manager), consept-trial@bristol.ac.uk (UK)

Study website
https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/consept/

Contact information

Type(s)
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
314206

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR133653, IRAS 314206, CPMS 54952

Study information

Scientific Title
CONservative versus Standard carE for primary spontaneous PneumoThorax (CONSEPT)

Acronym
CONSEPT

Study objectives
Conservative care compared to usual care reduces the number of subsequent pleural procedures over the first 30 days

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/01/2023, Wales REC 7 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, UK; +44 (0)2920 230457, (0)7920 565664; Wales.REC7@wales.nhs.uk); ref: 23/WA /0026

Study design
Open-label multicentre parallel-group-assignment two-group individually randomized controlled trial with an internal pilot phase

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 participant information sheet

Health condition(s) or problem(s) studied
Primary spontaneous pneumothorax

Interventions
This study is an open-label multicentre, parallel two-group, individually randomised controlled trial with an internal pilot phase, parallel cost-effectiveness analysis and active participant follow-up to 30 days.

Randomisation: Randomisation will be carried out using Sealed Envelope with stratification by study site and first/recurrent spontaneous pneumothorax.

Conservative Care: Participants randomised to conservative care should be managed without invasive intervention. They will be observed for a period of around four hours from the hospital presentation but the absolute observation period will be at the discretion of the treating clinician.

Usual Care: The comparator will reflect usual invasive care and comprise either needle aspiration or intercostal drain or pleural vent. The initial pleural procedure administered is at the discretion of the treating clinician.

Intervention Type
Mixed

Primary outcome measure
Any pleural procedure (intercostal drain insertion, needle aspiration, pleural vent, video-assisted thoracoscopy) measured using patient medical notes at any time after randomisation and completion of initial care up to 30 days after randomisation

Secondary outcome measures
1. Number of days in the hospital measured using patient medical notes up to 30 days after randomisation, including initial hospital stay and re-admissions
2. Pain and breathlessness measured using visual analogue scale (VAS) scores collected using an online application at baseline, 48 hours, and 14 and 30 days
3. Health-related quality of life measured using the participant-reported health status questionnaire (EQ-5D-5L) collected using an online application at baseline, 48 hours, and 14 and 30 days
4. Perceived participant acceptability of the intervention or comparator measured using a study-specific online questionnaire at 30 days
5. Radiographic resolution of PSP measured using a study-specific chest x-ray at 30 days
6. Adverse events measured using patient medical notes up to 30 days
7. Total number of subsequent pleural procedures measured using patient medical notes up to 30 days
8. Time to return to work (if employed) measured using a questionnaire at 30 days
9. Hospital resource use, including emergency, admitted, critical and outpatient care measured using routine data sources such as NHS Digital for up to 12 months
10. Time to recurrence of pneumothorax measured using routine data sources such as NHS Digital up to 12 months

Overall study start date
01/11/2021

Completion date
28/02/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 03/07/2025:
1. Symptomatic primary spontaneous pneumothorax of sufficient size to allow intervention
2. Aged between 16 and 50 years old (inclusive)

Previous key inclusion criteria:
1. Primary spontaneous pneumothorax of sufficient size and symptoms, where the treating physician is considering an intervention
2. Aged between 16 and 50 years old (inclusive)

Participant type(s)
Patient

Age group

Mixed

Lower age limit
16 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
164

Key exclusion criteria
Current key exclusion criteria as of 03/07/2025:
1. Known or suspected underlying lung disease*
2. Evidence of clinical tension pneumothorax
3. SpO2 <92% on air
4. Bilateral pneumothorax
5. Pregnancy
6. Inability to consent or comply with trial requirements

* Mild/well-controlled asthma is not considered an exclusion criterion. Patients with a diagnosis of asthma who are well-controlled on standard prescribed inhaler therapy remain eligible for participation in this study.

Previous key inclusion criteria:
1. Known or suspected underlying lung disease*
2. Evidence of clinical tension pneumothorax
3. SpO2 <92% on air
4. Bilateral pneumothorax
5. Pregnancy
6. Inability to consent or comply with trial requirements

* “Childhood asthma” or well-controlled 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
01/04/2023

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

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

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre

Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Queensview Medical Centre
Thornton Road
Northampton
United Kingdom
NN2 6LS

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Royal United Hospital
Combe Park

Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
The Guys and Lewisham NHS Trust
Guys Hospital
St Thomas Street
London
United Kingdom
SE1 9RT

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research and Innovation
North Bristol NHS Trust Floor 3
Learning & Research Building
Southmead Hospital
Westbury-on-Trym
Bristol
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United Kingdom
BS10 5NB
+44 (0)1174149330
ResearchSponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

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

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Presentations at conferences
3. Using mainstream and social media channels to let doctors know the findings

Intention to publish date
28/02/2028

Individual participant data (IPD) sharing plan
Data will not be made available for sharing until after publication of the main results of the study unless agreed by the Chief Investigator/Trial Management Group on a case by case basis. Thereafter, 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 MRC Policy on Data Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review.

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