

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

<b>Submission date</b> 21/12/2022	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/02/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### 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 CONCEPT 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 scheduled 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](mailto:consept-trial@bristol.ac.uk) (UK)

### **Study website**

<https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/consept/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Nick Maskell

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**Type(s)**

Public

**Contact name**

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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 hypothesis**

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

**Condition**

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

## **Overall study end date**

28/02/2027

# **Eligibility**

## **Participant 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**

638

**Participant exclusion 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.

**Recruitment start date**

01/04/2023

**Recruitment end date**

01/06/2026

**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?
<a href="#">HRA research summary</a>			26/07/2023	No	No