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Randomised controlled trial investigating needle aspiration versus chest drain for secondary spontaneous pneumothorax

Submission date 17/04/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/05/2023	**Overall study status** Completed	
Last Edited 15/04/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Secondary spontaneous pneumothorax (SSP) is where an abnormal collection of air develops in the space between the lung and the chest wall causing lung collapse. This type of pneumothorax is called secondary as it happens in patients with pre-existing lung conditions such as emphysema and is called spontaneous as it occurs without injury. Currently, SSP is typically treated by inserting a drain into the chest to remove the air. The drain usually stays in place for a week leading to a long hospital stay. A different procedure, needle aspiration, involves inserting a small plastic tube into the chest and removing the air with a syringe over roughly 20 minutes. This is a simpler procedure which means patients may avoid the need to have a chest drain. A previous small study found that patients spent less time in the hospital, and had fewer complications when treated with a needle aspiration. However, because only a small number of people were included in this study, we cannot be completely sure of the results. The PRINCE-SSP study would like to confirm these findings in a bigger study.

Who can participate?
Adults who have a symptomatic SSP if the pneumothorax is of sufficient size and symptoms would require intervention with a chest drain

What does the study involve?
Participants are randomised to receive either needle aspiration or chest drain (usual care). Needle aspiration involves inserting a small needle into the chest and the air is manually aspirated to remove the air. A chest drain involves the insertion of a drain into the chest wall which is stitched in place and attached to a drainage system. A chest drain stays in place for at least 24 hours and requires hospital admission. Needle aspiration takes approximately 20 minutes and is a one-off procedure. Participants will be asked some questions within the first 24 hours after their treatment and will receive a routine chest x-ray before they are discharged. Participants will be asked to complete some questionnaires on days 1 to 5 after their treatment and if they have been discharged home before day 5 they will be given a diary to take home and record some information. Participants will then attend a routine 30-day follow-up appointment where they will be asked some more questions and receive another chest x-ray. A researcher will

also look at relevant sections of participants' medical notes to record details of their care (e.g. how long they stayed in the hospital) and any complications they might have experienced.

What are the possible benefits and risks of participating?
Both treatments have advantages and disadvantages and this research will help determine whether doctors should change their practice for the treatment of SSP. There are no direct benefits from taking part in the trial. Both needle aspiration and chest drain are standard treatments used to treat various types of pneumothorax. If needle aspiration is not successful then a chest drain may need to be inserted after the needle aspiration to drain the air between the lung and chest wall. This could be seen as a delay in having the chest drained and the pneumothorax could worsen with time. Participants will be closely monitored throughout the study. Chest X-rays are performed as part of participants' routine care and participants will not undergo any additional chest X-rays in this trial.

Where is the study run from?
Multiple sites across England and Wales from within emergency departments or acute medical units (UK)

When is the study starting and how long is it expected to run for?
November 2022 to June 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme (UK)

Who is the main contact?
Dr Steven Walker (Co-CI), steven.walker@bristol.ac.uk (UK)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324020

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55271, IRAS 324020

Study information

Scientific Title
Pragmatic non-inferiority randomised trial investigating needle aspiration versus chest drain for secondary spontaneous pneumothorax

Acronym
PRINCE-SSP

Study objectives
Is the length of initial hospital stay in spontaneous secondary pneumothorax patients managed with needle aspiration no worse than for secondary spontaneous pneumothorax patients managed with a chest drain (usual care), whilst demonstrating benefits in other important patient-reported, clinical and cost-effectiveness outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2023, Wales REC 7 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, UK; +44 (0)2922 941107, (0)2922 940954, (0)2922 940968; wales.REC7@wales.nhs.uk), ref: 23/WA/0085

Study design
Multi-centre randomized controlled trial

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
Secondary spontaneous pneumothorax

Interventions
Study design:
- Randomised controlled trial to see if the intervention (needle aspiration, NA) is non-inferior to standard care (intercostal chest drain, ICD) in patients with secondary spontaneous pneumothorax (SSP), with respect to the initial length of hospital stay, patient-reported outcomes, clinical and cost-effectiveness outcomes.
- Emergency treatment delivered in emergency departments/acute medical units.
- 110 participants across 2 groups, 55 participants will receive NA and 55 will receive ICD.
- Multi-centre (aiming to recruit from roughly 15 UK NHS sites)
- Planned internal progression review after 6 months of recruitment considering the number of centres open and recruitment rates.
- Primary outcome measure is to test whether NA is non-inferior to ICD with respect to the initial length of hospital stay during 30 days from randomisation. If NA is non-inferior to ICD, assess whether NA is superior to ICD with respect to the initial length of hospital stay.
Recruitment:
- Potentially eligible participants will be identified by clinical and research teams in the emergency, acute medical and respiratory departments.
- Eligibility assessment will include a chest x-ray to confirm the presence of a pneumothorax.
- If participants are deemed to have the capacity to provide informed consent, a research nurse /clinician discusses the study with the patient and provides the summary and detailed PISs.
- If eligible, has the capacity and is willing to take part written informed consent is obtained either on a paper or electronic Informed Consent Form.
- If eligible, but lacks capacity, auto-enrolled into the study using the deferred consent model based upon HRA guidance on research in emergency settings.
- For those participants who regain capacity within the first 72 hours after randomisation, the information provided about the trial and what has likely happened so far, sign an informed consent form or withdraw.
- For those participants who do not regain capacity within the first 72 hours after randomisation, a consultee will be identified, the study is discussed, sign a consultee declaration form or withdrawn.
- The consent form includes the completion of the study questionnaires as an optional item.
Baseline:
- Minimal baseline data recorded before randomisation. Patient-reported outcome measures will be collected within 24 hours of randomisation and after treatment delivery.
- Demographics*, contact details, consultee details (if necessary)
- Eligibility assessment (pneumothorax details, chest x-ray**, smoking history, underlying lung disease)*
- Management of previous secondary spontaneous pneumothoraces
- Comorbidities
- National Early Warning Score
- Pain numeric rating scale
- MRC dyspnoea scale
- EQ-5D-5L
- SF-36
- Clinical Frailty Score
*To be collected before randomisation
**To be collected before randomisation (to assess eligibility) AND after intervention (for intervention evaluation). In the

NA group 1 x-ray will be performed post-intervention, in the ICD group 2 x-rays will be performed 1 after drain insertion and 1 after cessation of bubbling in the water seal (post-intervention).
Intervention:
- 55 participants will be treated with needle aspiration
- 55 participants will be treated with intercostal chest drain
Days 1 – 5
- Pain numeric rating scale
- MRC dyspnoea scale
- EQ-5D-5L*
- SF-36*
*To be collected only on day 5
For those discharged before day 5, a participant diary will be given to participants to capture this data.
Day 30
- Chest x-ray
- Length of hospital stay*
- Pleural interventions
- Clinical assessment
- Hospital re-admittance
- Resolution of SSP
- Pain numeric rating scale
- MRC dyspnoea scale
- EQ-5D-5L
- SF-36
- Clinical Frailty Score
*Date to death/discharge will try to be captured for participants who remain in the hospital beyond day 30
End of participation in the study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Length of initial hospital stay (LOHS) from randomisation measured using patient medical notes at Day 30 post-randomisation. Calculated to the nearest hour. Every attempt will be made to collect the date of discharge to calculate LOHS, even if past Day 30, for supporting analyses.

Secondary outcome measures
1. Pain measured using a numerical rating scale (NRS) daily for the first 5 days post-randomisation and day 30 post-randomisation
2. Breathlessness measured using the MRC dyspnoea scale daily for the first 5 days post-randomisation and Day 30 post-randomisation
3. Patient-reported health status measured using the EQ-5D-5L and SF-36 questionnaire on Day 5 post-randomisation, and Day 30 post-randomisation
4. Total number of days in hospital including readmissions measured using patient medical notes at Day 30 post-randomisation. Calculated to the nearest hour. Every attempt will be made to collect these dates of discharge to calculate LOHS, even if past Day 30, for supporting analyses
5. Immediate treatment success:
5.1. For NA, success is defined by persistent adequate responses following the aspirations.
5.2. For ICD, success is defined by an adequate response with the removal of a drain within 72

hours of drain insertion
6. Hospital readmission measured using patient medical notes on Day 30 post-randomisation
7. Fitness and frailty measured using the Clinical frailty score Post-intervention and Day 5 post-randomisation
8. Pneumothorax resolution on X-ray measured using patient medical notes on Day 30 post-randomisation
9. Total number of subsequent pleural procedures measured using patient medical notes within first 24 hours and up to 30 days post-randomisation
10. Mortality measured using patient medical notes Day 30 post-randomisation
11. Hospital resource use up to 30 days, including emergency, admitted, critical and outpatient care measured using patient medical notes on Day 30 post-randomisation
12. Cost effective and utility measured using a health economics resource use questionnaire on Day 30 post-randomisation

Overall study start date
01/11/2022

Completion date
06/06/2025

Eligibility

Key inclusion criteria
Adult patients (>=18 years of age) with symptomatic SSP will be potentially eligible if:
1. The pneumothorax is of sufficient size and symptoms for the treating physician to consider intervention with ICD, AND
2. The patient has an SSP, defined as a pneumothorax occurring in a patient:
2.1. With known underlying lung disease OR
2.2. >=50 years of age with significant smoking history OR
2.3. With suspected underlying lung disease with radiology confirming structural lung disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 110; UK Sample Size: 110

Key exclusion criteria
Patients will be excluded if there is:
1. Bilateral pneumothorax
2. Traumatic or iatrogenic pneumothorax

3. Clinical concerns of tension pneumothorax
4. Age <18 years of age
5. Known pregnancy

Date of first enrolment
01/06/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
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BS10 5NB

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Derriford Hospital
Derriford Road
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Sponsor type
Hospital/treatment centre

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

ROR

https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

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
14/10/2025

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. All trial data excluding personally identifiable information will be made available indefinitely. Consent from participants will be obtained for data to be stored for the purposes of other ethically approved research in the future and that data will be shared anonymously.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Protocol article		26/12/2024	17/01/2025	Yes	No