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A study to compare a single drainage procedure (therapeutic aspiration) versus a standard chest tube for the initial treatment of infected fluid around the lung

Submission date
18/12/2025

Recruitment status
Not yet recruiting

Registration date
09/01/2026

Overall study status
Ongoing

Last Edited
09/01/2026

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

When people get chest infections, fluid can sometimes build up around the lung. In about 1 in 10 cases, this pleural fluid itself becomes infected and needs drainage. This is called pleural infection. Pleural infection is a serious condition, affecting over 10,000 people per year in the UK. The condition can affect anyone but is more likely to affect those who are elderly or have a weakened immune system. These groups are also the most harmed by long stays in hospital. The current practice to remove the fluid is to insert a chest tube (about 6 mm across) between the ribs, to allow fluid to drain into a collection bottle. This tube stays in place until all the fluid has come out, which usually takes between 3-5 days, but it can take much longer. The drain can be sore and prevents people moving around normally. Patients need to stay in hospital whilst the drain is in position. As important as draining the fluid is treating the infection with antibiotics, but there is uncertainty about how well antibiotics work in the infected fluid and how best to give them (through the vein or as tablets). These uncertainties have meant that, unlike for other lung infections, the length of time patients stay in hospital is over a fortnight. These long hospital stays place a burden on the patient, their family, and the NHS. Patients are also given long courses of antibiotics through the vein (intravenous antibiotics), a problem for antibiotic resistance. This study aims to reduce the length of time patients with pleural infection need to stay in hospital by answering two linked questions. Firstly, can we drain the fluid in a better way? Using a less invasive single drainage approach called therapeutic thoracentesis for the infected fluid might allow patients to be more mobile. This study will show whether this approach can safely reduce the number of days patients need to stay in hospital. Secondly, can we improve antibiotic treatment for pleural infection?

Who can participate?

Patients aged 16 years and over admitted to participating hospitals with a pleural infection who satisfy the inclusion criteria and for whom none of the exclusion criteria apply

What does the study involve?
Patients will be randomly assigned to have their fluid drained using a chest tube or therapeutic thoracentesis. We will collect samples of pleural fluid from the patients and antibiotic levels within that fluid will be measured. We will test if how we drain the fluid affects the antibiotic levels. If so, this will encourage doctors to use shorter intravenous courses, removing another barrier to earlier hospital discharge.

What are the possible benefits and risks of participating?
We hope that every patient will gain benefit from the infected fluid being drained, whether it is from a chest tube or therapeutic aspiration. Whichever group you are allocated to, your participation in this study will contribute to our understanding and development of new and better ways of managing pleural infection. This will hopefully benefit patients in the future.
If you are allocated to therapeutic aspiration, there is a possibility that if safe, and with your agreement, you could go home sooner than you might have done with a chest tube.
Both treatments used in this study are regularly performed in the NHS to drain fluid from around the lung. There are very similar risks to both procedures, such as bleeding and discomfort. There is also a possibility that the initial chest tube or therapeutic aspiration does not completely resolve the infection and further treatments are required. Taking blood samples may cause bruising and may cause some people to feel faint.

Where is the study run from?
Oxford Respiratory Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
August 2024 to December 2029

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

Who is the main contact?
Dr David Arnold, David Arnold@nbt.nhs.uk

Contact information

Type(s)
Public, Principal investigator, Scientific

Contact name
Dr David Smith

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Additional identifiers

Central Portfolio Management System (CPMS)

58562

National Institute for Health and Care Research (NIHR)
159462

Integrated Research Application System (IRAS)
357237

Study information

Scientific Title
Initial Management of Pleural infection: Aspiration vs Chest Tube (IMPACT) trial

Acronym
IMPACT

Study objectives
Primary objective:
For adults who present to the hospital with pleural infection, does initial treatment with therapeutic thoracentesis reduce the length of initial hospital stay compared to insertion of a chest tube (standard care)?

Secondary objectives:
To investigate if the initial treatment with therapeutic thoracentesis changes:
1. Proportion of patients readmitted to hospital within 30 days following discharge
2. Total duration of intravenous antibiotic use
3. Number of pleural procedures performed by 90-day follow-up
4. Number of rescue therapies performed (fibrinolytics or surgery)
5. Patient-reported health-related quality of life (HRQoL) measurements at Day 7 and Day 90
6. Pleural thickening at Day 90 (measured on ultrasound)
7. Mortality at Day 90

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2025, Wales REC2 (Health and Care Research Wales, Cardiff, CF11 9AB, UK; +44 (0)2922941119, +44 (0)2922 940959; Wales.REC2@wales.nhs.uk), ref: 25/WA/0302

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of pleural infection

Interventions
This study is a prospective, multi-centre randomised controlled study with internal pilot and embedded antibiotic pharmacokinetic (PK) study of adult patients hospitalised with pleural infection. Patients are randomised to therapeutic thoracentesis (TT) or chest tube insertion as the initial pleural procedure to drain the infected pleural fluid.

At screening, patients will have informed consent and demographics taken and eligibility assessment performed. At baseline, patients will be randomised to either therapeutic thoracentesis or chest tube insertion as the initial pleural procedure to drain the infected pleural fluid. They will then have their medical, medication, Radiology results (chest x-ray and pleural ultrasound), RAPID score (a baseline severity score) and lab tests recorded. At baseline, patients will also have their intervention performed, Patient reported outcomes, EQ-5D and VAS questionnaires completed and if consented to, Blood and Pleural fluid sample collected.

Following screening, baseline assessment and randomisation there will be trial visits at Day 7 and Day 90. The focus of these will be the collection of clinical information to inform primary and secondary outcomes.

Whilst patients are having pleural procedures (either with TT or chest tube), pleural fluid and or samples, may be collected and stored for antibiotic analysis. This will be optional for both study sites and patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Length of initial hospital stay in days measured using patient records at Day 90 measured using patient records

Key secondary outcome(s))
1. Proportion of patients readmitted to hospital within 30 days following discharge, measured using patient records
2. Total duration of intravenous antibiotic use in days by 90-day follow-up, measured using patient records
3. Number of pleural procedures performed by 90-day follow-up, measured using patient records
4. Number of rescue therapies performed (fibrinolytics or surgery) by 90-day follow-up, measured using patient records
5. Patient-reported health-related quality of life (HRQoL) measured using EQ-5D-5L at day 7 and day 90
6. Pleural thickening at day 90 (measured on ultrasound) from patient records
7. Mortality at day 90, measured using patient records

Completion date
31/12/2029

Eligibility

Key inclusion criteria
Hospitalised adult patients with a clinical presentation consistent with pleural infection AND requiring initial pleural fluid drainage based on one of the following parameters:

1. Pleural fluid pH <=7.2
2. Pleural LDH >=900
3. Pleural fluid glucose <=4.0 mmol/L (or 72 mg/dl)
4. Pleural septations/loculation on ultrasound
5. Evidence of pleural infection on CT
6. Pleural effusion occupying >50% of hemithorax on chest radiograph
7. Age >= 16 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Excessive bleeding risk in view of the treating clinician
2. Previous pneumonectomy, chest tube/drain, indwelling catheter or recent surgery on side of current pleural infection
3. RAPID score (if calculable) >5 (indicating a high risk of mortality within 3 months)
4. Enrolment onto another study where the burden on the participant will be too high if they are enrolled onto both. Or if the enrolment onto both would compromise one or both of the study's objectives. To be decided on a case-by-case basis.

Date of first enrolment
02/03/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
England
WF1 4DG

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
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TS24 9AH

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
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ST4 6QG

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
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Study participating centre
NHS South Yorkshire Integrated Care Board
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S1 3FG

Study participating centre
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Trust Management
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Musgrove Park Hospital
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TA1 5DA

Sponsor information

Organisation
North Bristol NHS Trust

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the study chief investigator, Dr David Arnold (david.arnold@nbt.nhs.uk) following the publication of the trial findings.

IPD sharing plan summary
Available on request