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A global study of pleural infection causes, management, and outcomes

Submission date
03/02/2026

Recruitment status
Recruiting

Registration date
04/02/2026

Overall study status
Ongoing

Last Edited
03/02/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The INTERMITTENT study aims to improve our understanding of pleural infection, a condition where infected fluid or pus builds up in the space between the lungs and the chest wall. Pleural infection most commonly develops as a complication of pneumonia and can lead to severe illness, longer hospital stays, and even death. Standard treatment includes antibiotics and draining the infected fluid, but how this is done can vary significantly between countries and even between hospitals.
One reason for this variation is a lack of global evidence on how pleural infections present, which bacteria are responsible, how they are managed in practice, and how patients respond to different treatments. The INTERMITTENT study has been designed to help address these knowledge gaps.

The study has five key goals:
• To find out how common pleural infection is in different parts of the world and in different seasons.
• To identify the bacteria most often responsible.
• To describe the types of patients affected.
• To examine how pleural infection is treated globally.
• To assess how treatment affects patient recovery and outcomes.
By collecting this information, the researchers hope to improve the way pleural infection is recognised, diagnosed, and treated across the world, ultimately leading to better care and improved outcomes for patients.

Who can participate?
Patients aged 18 or over who underwent a pleural procedure for suspected pleural infection, with pleural fluid culture and chemistry, within the previous 4 weeks.

What does the study involve?
This international study will be carried out in multiple hospitals around the world. It will involve two 4-week data collection periods, one in winter and one in summer, to help researchers understand whether pleural infections vary with the seasons. Doctors will collect information about all patients diagnosed with pleural infection during those periods, including details such

as age, sex, location, medical history, test results, type of treatment received, and recovery over the following 12 weeks.

What are the possible benefits and risks of participating?
The benefits are that information from this study may improve our understanding and future treatment of pleural infection moving forward.

There are no anticipated risks of this study, as patient care will not be affected by taking part in the study. The study will only collect anonymised routine clinical data available from the medical records.

Where is the study run from?
University of Bristol, UK.

When is the study starting and how long is it expected to run for?
February 2026 to January 2027.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Steven Walker, steven.walker@bristol.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
360388

Protocol number
2025-4652

Study information

Scientific Title
The INTERnational MultIcenTer sTudy of piEural iNfecTion (INTERMITTENT): a point prevalence survey of the global aetiology, management and outcomes of pleural infection

Acronym
INTERMITTENT

Study objectives
Primary Objective:
To identify and describe international variations in terms of burden of disease and aetiology of pleural infection.

Secondary Objectives:
- To establish the number of pleural infections and to assess variations in prevalence by geographic location and seasonality.
- To establish the causative microorganisms of pleural infection in an international cohort and describe variations in microbiology by geographic location and seasonality.
- To describe demographic, clinical, and management strategies for pleural infections.
- To associate management strategies with clinical outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/11/2025, Health and Care Research Wales (HCRW) (Floor Four, North, Welsh Government Offices, Cathays Park, King Edward VII Avenue, Cardiff, CF10 3NQ, United Kingdom; +44 02920 230457; HCRW.approvals@wales.nhs.uk), ref: 25/HRA/5006

Primary study design
Observational

Secondary study design
Epidemiological study

Study type(s)

Health condition(s) or problem(s) studied
Pleural infection

Interventions
This will be an international, multicentre point prevalence survey (PPS).

Data collection will be over two 4-week periods within 12 months, from 1st to 28th February and 1st July to 28th July, to reflect the winter and summer seasons. There are two time points for data collection for each patient: at baseline and at 12 weeks. At the 12-week time point data will be collected retrospectively from the hospital clinical records. All data collection will be performed by a member of the clinical team. Anonymised data will be uploaded to a central REDCap database, and analysed for the outcomes defined below.

Baseline data collection will include:
Basic demographics: Age, Sex, Geographic location (country, city), Site of care (inpatient/ outpatient), and Medical history and comorbidities.

12-weeks Post-enrollment data collection will include:
- Details of the pleural procedure: date, type, indication, complications, ultrasound use
- Pleural fluid results: appearance, culture, biochemistry, cell count, mycobacterial culture
- Blood test results (within 1 week of initial pleural aspiration): WCC, CRP, platelets, albumin, urea, procalcitonin
- Radiology (within 1 week of initial pleural aspiration): size of effusion, laterality, additional features sen
- Treatment: antibiotics (drug, regimen, duration), intercostal drainage (size, insertion technique, duration), surgery, use of fibrinolytics (drugs, regimen, duration) and medical thoracoscopy (indication, findings, date)
- RAPID score
- 12 week outcomes: duration of hospital stay, mortality, need for surgery, re-admission to hospital.

In addition, the study will also collect information from each site regarding methods for pleural fluid collection and cultures including:
- Container for pleural fluid specimen collection (blood culture bottles, vs sterile specimen container vs other)
- Volume of pleural fluid sent for culture
- Laboratory processing of pleural fluid for culture
- Culture method (plating, liquid culture – especially for Mtb isolates)
- Sensitivity testing method (phenotypic, genotypic, NAAT etc)

Intervention Type
Not Specified

Primary outcome(s)
1. Incidence of pleural infection measured using data collected from hospital clinical records for cases per 100,000 at 12 weeks

Key secondary outcome(s))
1. Setting of pleural infection measured using data collected from hospital clinical records on geographic location and season of the year at baseline

2. Pleural microbiology measured using data collected from hospital clinical records on the frequency of specific microorganism isolation in pleural fluid at 12 weeks

3. Characterisation of pleural infection measured using data collected from hospital clinical records on the prevalence of major comorbidities in patients with pleural infection, biochemical characteristics of pleural fluid (pH, protein, lactate dehydrogenase, glucose etc), radiological presentation of pleural infection, and blood test results (CRP, WCC, Platelets etc) at 12 weeks

4. Management strategy measured using data collected from hospital clinical records on the choice of antibiotic for pleural infection treatment, duration of antibiotic regimen (days), type of drainage procedure used for pleural fluid, use of intrapleural fibrinolytic therapy, duration of intrapleural fibrinolytic therapy and type of surgical treatment (if applicable) at 12 weeks

5. Health outcomes measured using data collected from hospital clinical records on the duration of hospital stay (days), mortality rate at 12 weeks, requirement for surgical management for pleural infection, readmission to hospital within 12 weeks, and return to work within 30 days at 12 weeks

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Any patient aged 18 or over who underwent a pleural procedure for suspected pleural infection, with pleural fluid culture and chemistry, within the previous 4 weeks.

Definitions:
1.1. Suspected pleural infection will be identified by the treating/participating clinician, based on: Symptoms and signs suggestive of an infectious process including, but not limited to, one or more of:
1.1.1. Malaise
1.1.2. Fever
1.1.3. Chest pain
1.1.4. Cough
1.1.5. Raised white cell count
1.1.6. Raised C-reactive protein (CRP) or other inflammatory/infectious marker in blood
AND
Chest imaging evidence of a pleural effusion
1.2. A pleural procedure will be any procedure during which pleural fluid is aspirated from an effusion, in a patient fulfilling the criteria for suspected pleural infection above.
1.3. Pleural procedures where pleural fluid is aspirated but not sent for microbiological testing will not be included, except when the fluid is frank pus and another culture of blood or sputum has been sent.
1.4. Inpatients and outpatients may be included, and patients admitted to a high care or intensive care unit.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Patient is younger than 18 years.
2. Patient has suspected pleural infection as a result of recent thoracic trauma or surgery.
2.1. Note on an exception: patients who have suspected pleural infection and a recent pleural biopsy will still be included, provided there was a preexisting pleural effusion.
3. Patient is culture-positive for pulmonary or pleural Mycobacterium tuberculosis (TB)*.
4. Known pleural malignancy (pleural fluid cytology positive for malignant cells or known thoracic malignancy or metastases).
*It is recognised that patients from areas of high incidence of TB, pleural infection can present similarly to TB pleuritis. Patients will not be excluded solely based on high pretest probability of TB. Patients who are included initially and eventually diagnosed with pleural TB will be dealt with separately in the analysis

Date of first enrolment
01/02/2026

Date of final enrolment
01/01/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	03/11/2025	03/02/2026	No	No