ISRCTN98460319 https://doi.org/10.1186/ISRCTN98460319

A trial to investigate whether pleuroscopy can be used to treat pleural infection

Submission date
26/06/2017

Recruitment status
No longer recruiting

Registration date
03/07/2017

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A pleural effusion is a collection of fluid between the lung and the chest wall. It commonly occurs as a result of pneumonia and can cause significant breathlessness. In about 10% of cases, this fluid can itself go on to become infected, which increases the chances of someone becoming unwell enough to need surgery, or even dying. It is important that the fluid is drained away completely soon after someone is diagnosed with pleural infection. This is usually done by inserting a small chest tube between the ribs and allowing the fluid to drain out over time. This treatment typically requires many days in hospital but is generally low risk. Medical thoracoscopy is a common technique used to diagnose and drain effusions, although it is not routinely used for pleural infection in the UK as it tends to be reserved for those who are suspected of having cancer. It involves inserting a small camera between the ribs into the fluid and can be done under local anaesthetic. The procedure is very safe but carries a slightly higher risk of complications than standard chest tube insertion. However, the main benefit of the procedure is that it can allow a patient to spend less time in hospital because the chest is drained completely all at once. The aim of this study is to evaluate whether hospitals are able to safely offer medical thoracoscopy to patients with pleural infection

Who can participate?
Adults aged 18 and older who have pleural effusion.

What does the study involve?
Eligible participants are asked to answer questions about their background and previous health. Participants are randomly allocated to one of two groups that determined how their infected fluid is drained. Those in the first group receive the standard treatment, whereby a small tube is inserted between the ribs under local anaesthetic and the fluid is drained. Those in the second group receive the study treatment, which involves placing a small camera between the ribs to inspect and drain the fluid away. Participants are discharged after a few days in hospital. During their stay, participants receive standard care and treatment, but are also asked to perform simple breathing tests and answer some questions about their symptoms and quality of life. Participants are followed up at their local hospital by the trial team after one month and three months, when further information about their recovery and symptoms is gathered to see how the treatment affects patients themselves, and whether it is effective at reducing patients' time

in hospital or their need for surgery. About half of the patients enrolled will also be invited to take part in a more in-depth interview about their experiences in the trial.

What are the possible benefits and risks of participating?
There are no notable benefits with participating however participants are reimbursed for travel expenses. There are no notable risks however, there is normally some risk associated with any medical procedure and this will be discussed in detail with participants depending which treatment they are asked to undergo.

Where is the study run from?
This study takes place at Southmead Hospital (UK) and takes place in seven other hospitals in the UK.

When is the study starting and how long is it expected to run for?
July 2016 to January 2019 (updated 03/07/2019, previously: July 2018)

Who is funding the study?
Academy of Medical Sciences (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
33928

Study information

Scientific Title
Studying Pleuroscopy in Routine Pleural Infection Treatment Trial

Acronym
SPIRIT

Study objectives
Randomising patients with pleural infection to undergo either medical pleuroscopy or standard chest drain insertion is feasible and acceptable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Sheffield Research Ethics Committee, 12/04/2017, ref: 17/YH/0074

Study design
Randomised; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Respiratory disorders, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Other acute lower respiratory infections

Interventions
Those who agree to enrolled are first asked to answer questions about their background and previous health. Eligible participants are randomised in a 1:1 ratio using an online (computer-

based) system. Patients are randomised to receive one of two standard procedures. The intervention arm (medical pleuroscopy) entails a procedure lasting approximately 45 minutes. The control arm (chest drain insertion) consists of a procedure lasting approximately 15 minutes.

Intervention arm: Patients will undergo medical pleuroscopy on either the same or next day as they are diagnosed as needing a pleural intervention. They will have the procedure under light conscious sedation and local anaesthetic.

Control arm: Patients will undergo routine chest drain insertion on either the same or the next day as they are diagnosed as needing a pleural intervention. The procedure will be performed under local anaesthetic.

Patients with pleural infection can usually be discharged home after a few days in hospital. During their stay, participants receive standard care and treatment, but are also asked to perform simple breathing tests and answer some questions about their symptoms and quality of life. Participants are followed up at their local hospital by the trial team after one month and three months, when further information about their recovery and symptoms is gathered. About half of the patients enrolled will also be invited to take part in a more in-depth interview about their experiences in the trial.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The feasibility of screening and enrolling patients into the study, and delivering the trial protocol is measured using the proportion of pre-screen failures, screen failures, and allocation failures compared to the total numbers of patients pre-screened, screened, and randomised (respectively).

Key secondary outcome(s))
1. Duration of stay due to pleural infection is measured by the number of nights in hospital between enrolment and being recorded as medically fit for discharge
2. Total inpatient time is measured by the number of nights in hospital between enrolment and the end of the 90-day post-procedure follow-up period
3. Need for step-up therapy is measured by the difference in proportion of patients requiring intrapleural fibrinolytic therapy or referral for surgical debridement
4. Lung function is measured by the change in spirometry values (FEV1,FVC and FEV1:FVC ratio) at baseline and days 30 and 90
5. All-cause mortality is measured by the number of patients remaining alive at days 30 and 90 post procedure
6. Degree of pleural fluid septation is measured by the change in bedside thoracic ultrasound septation score at baseline and days one, three, seven, 30 and 90 post procedure
7. Pleural effusion size, is measured by the change in radiographic hemithorax opacification from enrolment to discharge, and days one, 30 and 90 post procedure
8. Microbiological yield is measured by the difference in proportion with positive culture or stain between the control and intervention arms at 90 days
9. Total costs of interventions is measured by the difference in total cost of treatment for pleural infection (from enrolment to being medically fit for discharge) between two arms at 90 days post procedure
10. Quality of life is measured by the change in EQ-5D subjective health score at baseline to days 30 and 90 post procedure

11. Patient experiences are assessed by exploring patients' perceptions and experiences of interventions before and after their procedure through semi-structured interviews at baseline and study end

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. Pleural effusion due primarily to suspected pleural infection requiring chest tube drainage, defined as an effusion, in the appropriate clinical context, with one or more of the following characteristics:
1.1. Fluid pH ≤7.20 or visually contains pus
1.2. Pleural fluid glucose ≤3.4 mmol/L
1.3. Positive bacterial or mycobacterial culture
1.4. Positive gram stain or stain for acid-fast bacilli
2. Clinical team are able to perform a medical thoracoscopy, if allocated, on either the same or the next day as the effusion is diagnosed as requiring drainage
3. Clinical team are able to deliver the post-procedure trial schedule as detailed in the protocol
4. Patient is willing to consider trial entry and receive information sheet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Any contraindication, in the opinion of the trial team or lead clinician, to
1.1. Medical thoracoscopy performed under conscious sedation
1.2. Chest drain insertion
1.3. Trial involvement
2. Patient is unable to provide informed consent
3. Thoracic imaging demonstrating septation or loculation to a degree whereby medical management alone would be inappropriate
4. Maximum pleural fluid depth of ≤2cm on thoracic ultrasound
5. Ongoing sepsis requiring haemodynamic support beyond basic fluid resuscitation
6. Previous thoracic surgery on the side of the effusion

7. Age <18
8. Pregnancy or lactation
9. Expected survival ≤3 months

Date of first enrolment
01/08/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Scotland

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

Study participating centre
Gloucester Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Wythenshawe Hospital
University Hospital of South Manchester NHS Foundation Trust
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Queen Elizabeth University Hospital Glasgow
NHS Greater Glasgow and Clyde
1345 Govan Road
Glasgow
Scotland
G51 4TF

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Sharoe Green Lane North
Fulwood
Preston
England
PR2 9HT

Sponsor information

Organisation
Southmead Hospital

ROR

https://ror.org/05d576879

Funder(s)

Funder type
Charity

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at North Bristol NHS Trust.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/12/2025	30/12/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.1	06/04/2018	24/08/2022	No	No