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Comparing aspiration to chest tube drainage for treating infected fluid around the lung

Submission date
29/04/2019

Recruitment status
No longer recruiting

Registration date
05/12/2019

Overall study status
Completed

Last Edited
31/08/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
When people get chest infections, fluid can sometimes build up around the lung. This is called a pleural effusion. In about 1 in 10 cases, the fluid itself becomes infected, this is called pleural infection. Pleural infection is usually treated by removing the infected fluid, and using antibiotics to mop up the left-over infection. The most common method to remove the fluid is to insert a chest tube (about 6 mm across) through the chest wall, to allow fluid to drain into a collection bottle. This tube stays in until all the fluid has come out, which is usually between 3-5 days, although it can be 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. The average hospital stay for pleural infection is 13 days, placing a significant burden on patients, their families, and the health service.
An alternative to chest tube drainage is a procedure called therapeutic thoracentesis (TT). This involves inserting a smaller (3 mm) tube into the fluid and drawing off as much as possible, over 20 minutes or so, before removing the tube. This can be repeated if the fluid builds up again. This method allows patients to move around freely between procedures and even be managed out of hospital. However, it is not known whether TT might mean it takes longer for the infection to fully clear. Although some hospitals in Europe use TT for pleural infection, no studies have ever directly compared chest tubes to TT.
This study is a feasibility (test) study to assess whether a full-scale trial would be possible, safe and acceptable for patients. Before starting, the researchers will involve patients who have had pleural infection to get their input on improving the trial design and processes.

Who can participate?
Patients admitted to Southmead Hospital with pleural infection

What does the study involve?
Participants are randomly allocated to have either chest tube or TT. Information on hospital stay and quality of life is collected. However, the main outcome is whether a full-scale trial would be possible (were participants willing to take part). The researchers also interview patients and health professionals who took part to get their opinions on the trial processes and possible improvements.

What are the possible benefits and risks of participating?
It is hoped that every patient will gain benefit from the infected fluid being drained whether it is from a standard chest tube or therapeutic aspiration. Whichever group patients are allocated to, participation will contribute to the understanding and development of new and better ways of managing pleural infection. This will hopefully benefit similar patients in the future. If patients are allocated to therapeutic aspiration there is a possibility that if safe, and with their agreement, they could go home sooner than they might have done with a standard chest tube. In terms of disadvantages, both treatments used in this study are regularly performed in the NHS to drain fluid from around the lung. There are similar risks to both procedures, such as bleeding or 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. Finally, if patients are allocated to the therapeutic aspiration treatment and are discharged home there is a possibility of being readmitted to hospital if the infection does not improve.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2019 to April 2022 (updated 05/01/2021, previously: April 2021)

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

Who is the main contact?
Dr David Arnold
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number

4563; CPMS: 42473

Study information

Scientific Title
Aspiration versus Chest Tube drainage in pleural infectION trial (ACTion)

Acronym
ACTion

Study objectives
Pleural infection management is hospital-centric due to the requirement for chest tube insertion. There are other methods for draining the infected fluid that may allow the patient to ambulate and be discharged quicker. One such method is therapeutic thoracentesis. The researchers intend to perform a randomized feasibility to see if a full-scale trial of chest tube versus therapeutic thoracentesis could be performed in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/07/2019, Wales REC 7 (Public Health Wales Building, 1 Jobswell Road, St David's Park, SA31 3HB; Tel: +44 (0)126761164; Email: WalesREC7@wales.nhs.uk), REC ref: 19/WA/0200

Primary study design
Interventional

Study design
Feasibility randomized trial

Study type(s)
Treatment

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

Interventions
At the time of diagnosis of pleural infection, potential patients are approached to be invited to participate. Patients will be randomized 1:1 using the REDCap randomisation module (stratified by size of pleural effusion on chest x-ray) to chest tube (standard care) versus therapeutic aspiration (intervention) to drain their infected pleural space.

Total duration of treatment: non-specific but estimated to be around 14 days
Follow up: 90 days

Intervention Type
Procedure/Surgery

Primary outcome(s)

The feasibility of a randomised trial of chest tube versus thoracentesis in pleural infection, assessed by the proportion of the total number of patients who are eligible for trial entry that accept randomisation. The primary outcome will be defined as successful if ≥50% of eligible patients are willing to be randomised. Measured at randomisation.

Key secondary outcome(s)
1. Number of pleural procedures required before resolution of infection, measured using cumulative totals at 90 days
2. Requirement for intrapleural fibrinolytics, measured using cumulative totals at 90 days
3. Hospital Length of Stay (days) and readmission rates measured using cumulative totals within 30 days
4. Number of patients requiring surgical intervention measured as a proportion of the total number randomised at 30 and 90 days
5. All-cause mortality measured by the number of patients alive at days 30 and 90
6. Validity of lung function testing (measured as % predicted of forced volume vital capacity) at 90 days
7. Patient-reported outcomes measures (PROMS), including health-related quality of life (HRQoL)-using the EQ-5D-5L questionnaire and Visual Analog Score (VAS) for chest pain and shortness of breath at baseline, day 3, day 7, day 30 and day 90
8. Total costs of interventions, measured by the difference in costs between the treatment arms at 90 days. In order
to complete a health economic analysis, information on additional visits to primary or secondary care, social care
and informal carer costs will be collected
9. Pleural thickening measured using chest radiograph at baseline and 90 days

Completion date
30/04/2022

Eligibility

Key inclusion criteria
Patient meeting criteria for pleural infection or complex parapneumonic effusion requiring drainage using international definition (see below):
1. Purulent pleural fluid
2. Pleural fluid pH ≤ 7.2
3. Pleural fluid glucose ≤ 3.4 mmol/L
4. Pleural fluid gram stain and/or culture positive for bacteria
5. Large effusion occupying >50% of hemithorax

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. RAPID score 5 to 7 (higher risk of mortality)
2. Severe septations/locations on ultrasound (assessed using a validated scoring system)
3. Ongoing sepsis requiring support beyond basic fluid resuscitation
4. Uncorrectable coagulopathy
5. Unable to consent for study
6. Previous pneumonectomy, recent thoracic surgery or indwelling pleural catheter on side of pleural infection
7. Age < 18 years
8. Lives alone with no access to a telephone

Date of first enrolment
04/09/2019

Date of final enrolment
30/01/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
Please email Dr David Arnold (david.arnold@nbt.nhs.uk) for access to anonymised datasets. Patients will have given consent (when being recruited) for their anonymised data to be shared with third parties. There should be no ethical or legal restrictions. This data will be available on publication of the results of the trial (anticipated to be September 2021 and will be available for 5 years).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/08/2022	31/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Preprint results		22/04/2022	10/08/2022	No	No
Protocol file	version 4.0	05/01/2021	10/08/2022	No	No