

The British Thoracic Society trial to assess the safety and efficacy of intra-pleural streptokinase in pleural infection

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G9721289

Study information

Scientific Title

Study objectives

To evaluate the efficacy and safety of intrapleural streptokinase given to patients with complicated parapneumonic effusions and empyema to improve pleural drainage

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory disease

Interventions

500 Hospital inpatients randomised 1 to 1 to intra-pleural streptokinase or placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary Endpoints

a. Therapeutic failure requiring thoracic surgery or death

1. At 3 months and

2. At 1 year post-randomisation

b. Serious or severe adverse events

The definition of therapeutic failure requiring thoracic surgery will be left to the discretion of the managing physician

Secondary endpoints

a. Duration of hospital stay

b. Residual chest radiograph abnormality at three months post-randomisation

c. Lung function at three months post-randomisation

Key secondary outcome(s)

Not provided at time of registration

Completion date

07/08/2003

Eligibility

Key inclusion criteria

1. Purulent or positive Gram stain or positive culture pleural fluid
2. Acidic pleural effusion (pH less than 7.2) in the presence of clinical pneumonia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age less than 18 years
2. A serious illness making survival at three months unlikely.
3. Previous intrapleural fibrinolytics for this empyema
4. Previous video assisted thoracoscopic drainage, thoracotomy, pleural decortification or open drainage for this empyema
5. Known sensitivity to streptokinase.
6. Coincidental stroke or major haemorrhage
7. Major surgery within previous 5 days
8. Previous pneumonectomy on same side of infection.
9. Pleural malignancy
10. Females who are pregnant or lactating

Date of first enrolment

01/01/1999

Date of final enrolment

07/08/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Respiratory Trials Unit
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/03/2005		Yes	No

