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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 07/09/2009	**Condition category** Respiratory	

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, Medical Research Committee and Advisory 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				

Results article	03/03/2005	Yes	No