ISRCTN39138989 https://doi.org/10.1186/ISRCTN39138989

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

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| **Submission date**<br>25/10/2000 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>25/10/2000 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/09/2009 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/1999

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
500

### 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**
England

United Kingdom

**Study participating centre**
**Respiratory Trials Unit**
Oxford
United Kingdom
OX3 7LJ

# Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

**Sponsor details**
20 Park Crescent
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**Sponsor type**
Research council

**Website**
http://www.mrc.ac.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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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 |