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The second multi-centre intra-pleural sepsis trial (MIST2), to assess whether DNase or Alteplase, improve pleural fluid drainage in pleural infection

Submission date 24/05/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2004	**Overall study status** Completed	
Last Edited 15/08/2011	**Condition category** Infections and Infestations	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=46

Contact information

Type(s)
Scientific

Contact name
Dr Najib Rahman

Contact details
Academic Clinical Lecturer
Oxford Respiratory Trials Unit
University of Oxford
Churchill Hospital
Old Road, Headington
Oxford
United Kingdom
OX3 7LJ

Additional identifiers

EudraCT/CTIS number
2004-000658-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Multi-centre Intra-pleural Sepsis Trial (MIST2)

Study objectives
Pleural infection - an infection of the area around the lungs - can occur when people have lung diseases such as pneumonia. Doctors often try to drain the fluid around the lungs to try to treat this. But sometimes this can be hard to do successfully. Some people have to have an operation, and some people may die as a result of the infection. Researchers think that the drugs DNase and Alteplase, which are already used to treat other illnesses, might help to treat pleural infection. The MIST2 trial aims to test whether these drugs are safe, and whether they can help to drain the fluid around the lungs. We are doing this trial in partnership with the Respiratory Trials Unit at the Churchill Hospital, Oxford.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Eastern Multi-Research Ethics Committee (latterly Cambridgeshire 4 REC) on 16/12/2004 (ref: 04/mre05/53)

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
Pleural infection

Interventions
Patients will be randomly assigned in the ratio 1:1:1:1 to either of the following regimes:
Alteplase 10 mg bd (twice a day) intrapleurally + DNase 5 mg bd intrapleurallly; or
Alteplase placebo intrapleurally + DNase 5 mg bd intrapleurally; or
Alteplase 10 mg bd intrapleurally + DNase placebo intrapleurally; or
Alteplase placebo intrapleurally + DNase placebo intrapleurally.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary endpoint will be radiographic improvement in area of pleural collection (between the area of the pleural collection on the CXR at randomisation and the chest radiograph taken on day 6/7).

Secondary outcome measures
Secondary outcome measure(s):
1. Changes in blood CRP from baseline to day 6/7
2. Time from randomisation to remain apyrexial for 36 hrs
3. Total pleural fluid drainage
4. Survival and need for surgery at 3 and 12 months

Overall study start date
11/10/2003

Completion date
11/10/2007

Eligibility

Key inclusion criteria
1.A clinical presentation compatible with pleural infection
2. Has pleural fluid requiring drainage which is either purulent, gram stain positive, culture positive or acidic with a pH<7.2
3. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Added as of 10/09/2007: 210

Key exclusion criteria
1. Age <18 years
2. Has previously received intra-pleural fibrinolytics or DNase for this empyema
3. Has a known sensitivity to DNase or tissue plasminogen activator
4. Has had a coincidental stroke, a major haemorrhage or major trauma
5. Has had major surgery in the previous 5 days
6. Has had a previous pneumonectomy on the side of infection
Patients who are pregnant or lactating (females of childbearing potential must have a negative pregnancy test before randomisation)
Expected survival less than three months from a different pathology to this empyema (e.g. metastatic lung carcinoma)
Inability to give informed consent

Date of first enrolment
11/10/2003

Date of final enrolment
11/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Clinical Lecturer
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
R&D Office
Manor House
The John Radcliffe Hospital
Headley Way
Headington
Oxford
England

United Kingdom
OX3 9DU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Unrestricted educational grant from Roche UK

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	11/08/2011		Yes	No