

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

<b>Submission date</b> 24/05/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/10/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/08/2011	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=46](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=46)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2004-000658-22

### Protocol serial number

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

## Study type(s)

Treatment

## 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 intrapleurally; 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(s)**

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).

**Key secondary outcome(s)**

Secondary outcome measure(s):

1. Changes in blood CRP from baseline to day 6/7
2. Time from randomisation to remain afebrile for 36 hrs
3. Total pleural fluid drainage
4. Survival and need for surgery at 3 and 12 months

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**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**

United Kingdom

England

**Study participating centre****Academic Clinical Lecturer**

Oxford

United Kingdom

OX3 7LJ

## **Sponsor information**

**Organisation**

Oxford Radcliffe Hospitals NHS Trust (UK)

**ROR**

<https://ror.org/03h2bh287>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Unrestricted educational grant from Roche UK

## **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?
<a href="#">Results article</a>	results	11/08/2011		Yes	No