

Randomised controlled trial of fibrinolytic aided pleural drainage during chemical pleurodesis for malignant pleural effusion

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 05/03/2020	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

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
N0176008571

Study information

Scientific Title

Randomised controlled trial of fibrinolytic aided pleural drainage during chemical pleurodesis for malignant pleural effusion

Study objectives

Some patients with cancer become breathless because fluid, repeatedly collects in the space between the lung and the chest wall (the pleural cavity). To control this problem fluid is drained from the cavity and then the walls of the cavity can be 'stuck together' with an irritant solution. This often fails when the fluid in the chest is collected into separate locules and so the fluid does not drain effectively. This study assesses whether improving the draining of such loculated fluid with streptokinase improves the efficacy of the subsequent irritant solution 'sticking process'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malignant pleural effusion

Interventions

A randomised controlled trial

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Time to first post pleurodesis aspiration
2. Time to first increase in pleural shadow on chest radiograph
3. Number of patients requiring a further pleural drainage before death or two years follow-up (FU)

Key secondary outcome(s)

Not provided at time of registration

Completion date

04/03/2004

Eligibility

Key inclusion criteria

40 patients:

1. Confirmed pleural malignancy
2. Recurrent symptomatic pleural effusion
3. Aged 18-85

40 control patients, same criteria.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

All

Key exclusion criteria

Previous pleurodesis

Date of first enrolment

15/01/1998

Date of final enrolment

04/03/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oxford Centre for Respiratory Medicine

Oxford

United Kingdom
OX3 7LJ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration