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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 05/03/2020	**Condition category** Cancer	

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
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 clollected 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

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Malignant pleural effusion

Interventions
A randomised controlled trial

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
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)

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/01/1998

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Previous pleurodesis

Date of first enrolment
15/01/1998

Date of final enrolment
04/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Centre for Respiratory Medicine
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oxford Radcliffe Hospitals NHS Trust (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