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A study to compare the efficiency of sterile talc, tetracycline and bleomycin as sclerosing agents for medical pleurodesis in the treatment of malignant pleural effusions

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/12/2015	**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

Contact name
Dr M Henry

Contact details
Department of Respiratory Medicine
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436099009

Study information

Scientific Title
A study to compare the efficiency of sterile talc, tetracycline and bleomycin as sclerosing agents for medical pleurodesis in the treatment of malignant pleural effusions

Study objectives
To compare the efficacy of these three agents in preventing recurrence of malignant pleural effusion in a randomised controlled trial setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised three-arm active-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
Randomised controlled trial. Random allocation to:
1. Sterile talc
2. Tetracycline
3. Bleomycin

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
This study should provide information as to which of these most commonly used agents for medical pleurodesis is most effective in preventing further malignant pleural effusions. It should provide information on which agent if any is associated with more prolonged survival. It should provide information on issues such as pain and infection rates during pleurodesis with these agents. Hopefully, these data will lead to an evidence based choice of sclerosing agent for cancer patients with malignant pleural effusions.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2001

Completion date
01/06/2004

Eligibility

Key inclusion criteria
Predominantly lung cancer patients with a selection of other cancer patients with malignancy effusions. (This is likely to be mostly breast cancer patients.)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2001

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching 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