

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

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised three-arm active-controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

St James's University Hospital

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration