ISRCTN35591640 https://doi.org/10.1186/ISRCTN35591640

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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
07/12/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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
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

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