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Talc Pleurodesis: A Comparative Pilot Study Comparing Doctor vs Nurse Lead Procedure

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
27/06/2011

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0542172083

Study information

Scientific Title

Study objectives

Within many hospitals the procedure of talc slurry instillation to induce pleurodesis (talc pleurodesis) is traditionally undertaken by physicians. Anecdotal evidence suggests that this is not a uniform approach and in some hospitals, the procedure is performed by nurses. It is suggested that appropriately trained nurses could competently perform this procedure to the benefit of their patients.
The purpose of this study is to compare outcomes when the procedure is performed by medical staff and nursing staff, notably pain and anxiety, infection and increasing oxygen requirement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre, randomised pilot study

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Respiratory: Talc pleurodesis

Interventions
This is a multi-centre, randomised pilot study. Although this is a pilot study, it is recommended that individuals will be randomly allocated to prevent bias. They will be randomised to have the procedure performed either by a senior band nurse (F grade / Level 6 and above) or by a doctor. Following Local Research Ethics Committee approval, all patients meeting the study inclusion criteria will be invited to take part. Patients will be stratified according to Eastern Cooperative Oncology Group (ECOG) Performance Status to balance randomisation, so that each group is representative of the population being studied. The procedure protocol is well established and will be adhered to in both groups. Institutional limitations dictate that randomisation will be done using sealed envelopes, rather than computer generated. This will be done independently by the MRC statistician within the Research & Development Department at Papworth Hospital. Investigators will be required to telephone the department to obtain the randomisation group and study number, once the patient has signed the informed consent.

This study will compare outcomes when the procedure of talc pleurodesis is performed by a core group of senior nursing staff, compared to medical staff. The same procedure protocol will be adhered to by both groups. Both doctors and nurses will be taught how to perform the procedure by a Consultant in Chest Medicine, or a Senior Specialist Registrar identified by the Consultant as someone who is skilled and competent in performing talc pleurodesis. An educational package has been designed by the chief investigator, in collaboration with Consultant medical staff, to assist the individuals performing the procedure with self-directed learning. Evidence will be required to demonstrate their understanding of the indications and contra-indications for talc pleurodesis, as well as recognition of complications post-procedure and actions required.

The assessment of the most suitable time to perform the procedure, with regard to drainage of effusion and radiographic appearance will be decided by the medical team responsible for the care of the patient. This decision will NOT be made by the nursing staff. Prescribing of the talc will also be the responsibility of the medical staff.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Complications defined as pain, infection, increasing oxygen requirement
2. Pain and anxiety will be assessed using a Numerical Rating Scale
3. Infection will be measured according to positive culture and antibiotic therapy
4. Pulse oximetry will be measured prior to the procedure and at six hourly intervals following the procedure, in accordance with local practice. A drop in oxygen saturation below 90% will be supplemented with oxygen therapy as prescribed by the doctor.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/08/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

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
07/02/2006

Date of final enrolment
31/08/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Papworth Everard
Cambridge
United Kingdom
CB3 8RE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Papworth Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/08/2007		No	No