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

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| **Submission date**<br>29/09/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>29/09/2006 | **Overall study status**<br>Completed | |
| **Last Edited**<br>27/06/2011 | **Condition category**<br>Respiratory | |

**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**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Not Specified

## Participant information sheet

## 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 measure
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.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
07/02/2006

### Completion date
31/08/2006

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### 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**
07/02/2006

**Date of final enrolment**
31/08/2006

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Papworth Everard**
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# Sponsor information

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

**Sponsor details**
The Department of Health, Richmond House, 79 Whitehall
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**Sponsor type**
Government

**Website**

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

# Funder(s)

**Funder type**
Government

**Funder Name**
Cambridge Consortium - Papworth Hospital 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

**Study outputs**

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