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Assessment of new portable chest drain system versus conventional chest tube drainage in patients with primary spontaneous pneumothorax requiring pleural drainage

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 05/12/2014	**Condition category** Respiratory	[_] 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 CWH Davies

Contact details
Department of Respiratory Medicine
Royal Berkshire & Battle Hospitals NHS Trust
Abbey Block
Oxford Road
Reading
United Kingdom
RG30 1AG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0199104506

Study information

Scientific Title
Assessment of new portable chest drain system versus conventional chest tube drainage in patients with primary spontaneous pneumothorax requiring pleural drainage

Study objectives
Whether patients with pneumothorax can be managed effectively as outpatients with new portable chest drain (Vent).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised open label

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory: Pleural drainage

Interventions
Randomised open label design standard in patient drain or the Vent with option of early discharge. New portable chest drain system versus conventional chest tube drainage.

Intervention Type
Device

Primary outcome measure

1. Pain scale
2. Patient satisfaction
3. Length of hospital stay and economic savings
4. Complications of drainage

Secondary outcome measures
1. Time to resolution of pneumothorax
2. Successful resolution
3. Failures requiring surgery

Overall study start date
10/08/2001

Completion date
30/11/2004

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
10/08/2001

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Berkshire & Battle Hospitals NHS Trust
Reading
United Kingdom
RG30 1AG

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
Royal Berkshire and Battle 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