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A randomised controlled trial to assess the efficacy and safety of patient controlled maligant pleural effusion drainage by indwelling ambulatory pleural catheter, compared to standard care

Submission date
07/03/2007

Recruitment status
No longer recruiting

Registration date
30/04/2007

Overall study status
Completed

Last Edited
19/05/2014

Condition category
Respiratory

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

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=48

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-006630-18

Protocol serial number
TIME 2

Study information

Scientific Title

Acronym
The second therapeutic intervention in malignant effusion trial (TIME2)

Study objectives
A cancer induced collection of fluid between the lung and the chest wall (a pleural effusion) affects about 250,000 new patients each year (UK&US), including 25% of patients with lung cancer, 95% with mesothelioma and 40% with breast cancer. The accumulated fluid compresses the lung causing disabling breathlessness that requires painful pleural procedures to drain the fluid. Standard care includes adhering the lung to the chest wall (pleurodesis) which is painful and must be repeated in about 20% of patients. This is then followed by repeated fluid drainage if it fails. These procedures carry significant costs.
The advent of tunnelled ambulatory small-bore chest catheters, drained as required by patients and their carers, presents a different and potentially better strategy. Treatment could be almost entirely outpatient, with the patient controlling their drainage and free from the pain and costs of pleurodesis/drainage; though with the disadvantage of the indwelling catheter. Patients able to promptly drain their own catheter as needed should produce better breathlessness control than intermittent hospital treatment (the primary aim of pleurodesis). This study is a randomised trial which will compare how well breathlessness is controlled by an indwelling catheter compared to standard care in 114 patients with cancer induced pleural effusion and will measure the frequency of problems with the two treatment strategies. If this trial is positive, it will directly improve care for one of the commonest respiratory problems, to the benefit of >250, 000 patients each year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Milton Keynes Local Research Ethics Committee (ref: 07/Q1603/2)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pleural effusion

Interventions

Patients will be randomly assigned (1:1) to either an indwelling ambulatory pleural catheter or standard care for their malignant pleural effusion.
Computer derived allocation will be delivered by the established Oxford/London MRC Clinical Trials Unit systems. In order to minimise biases in trial results randomisation will include minimisation for histological tissue type (mesothelioma vs. non-mesothelioma) as survival is increased in mesothelioma, and the risk of catheter associated subcutaneous tumour invasion may be higher with mesothelioma, and for WHO performance status (0/1 vs. 2/3).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome will be the average daily Visual Analogue Scale (VAS) defining breathlessness, after removing "breathlessness unresponsive to pleural fluid drainage" - defined as the VAS following first complete pleural fluid drainage. Patients will also record how much their breathlessness has bothered them each day. The daily VAS will be performed at a similar time each day. The patients will perform VAS and record breathlessness for 6 weeks.

Key secondary outcome(s))
The following will be assessed at time of the primary outcome measure and recorded throughout the year of the trial:
1. Average daily chest pain assessed using VAS score for 6 weeks
2. Self reported health status (quality of life) assessed using Chronic Respiratory Disease Questionnaire (CRDQ) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C-30)
3. Economic assessment: direct quantification of clinical costs from patient kept diary records and estimated health care costs (Euroqol-5 Dimensions [EQ-5D] Questionnaire)
4. Spontaneous pleurodesis rate with ambulatory catheters (This will differ for each patient and will be recorded individually)
5. Complication rate with ambulatory catheters (Any complications that arise will be documented throughout the duration of the study)

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Clinically confident diagnosis of malignant pleural effusion requiring pleurodesis. The diagnosis may be established by:
a. Histocytologically proven pleural malignancy or
b. Recurrent large pleural effusion in the context of histologically proven cancer outside the thorax.
2. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Age < 18 years
2. Beginning chemotherapy in the next 4 weeks
3. Expected survival <3 months
4. Chylothorax
5. Previous lobectomy or pneumonectomy on the side of the effusion
6. Previous attempted pleurodesis
7. Pleural infection
8. Total blood white cell count <1.0 x 109
9. Hypercapnic ventilatory failure
10. Patients who are pregnant or lactating
11. Irreversible bleeding diathesis
12. Irreversible visual impairment
13. Inability to give informed consent or comply with the protocol

Date of first enrolment
01/04/2006

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Respiratory Trials Unit
Oxford
United Kingdom
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
British Lung Foundation (UK)

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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?
Results article	results	13/06/2012		Yes	No
Results article	results	01/10/2014		Yes	No