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	 Prospectively registered Protocol
Registration date 30/04/2007	Overall study status Completed	[_] Statistical analysis plan[X] Results
Last Edited 19/05/2014	Condition category Respiratory	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

EudraCT/CTIS number 2006-006630-18

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised controlled trial **Study setting(s)** Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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)

Overall study start date

01/04/2006

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

Age group

Adult

Sex Not Specified

Target number of participants

114

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

England

United Kingdom

Study participating centre Respiratory Trials Unit Oxford United Kingdom OX3 7LJ

Sponsor information

Organisation University of Oxford (UK)

Sponsor details Clinical Trials and Research Governance Manor House The John Radcliffe Hospital Headington Oxford England United Kingdom OX3 9DZ

Sponsor type University/education

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

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