

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

<b>Submission date</b> 07/03/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=48](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=48)

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Emma Hedley

### Contact details

Respiratory Trials Unit  
Oxford Centre for Respiratory Medicine  
Churchill Hospital  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 7LJ

## 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 10<sup>9</sup>
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

OX3 7LJ

**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?
<a href="#">Results article</a>	results	13/06/2012		Yes	No
<a href="#">Results article</a>	results	01/10/2014		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes