

A trial looking at quality of life in the treatment of patients with malignant pleural effusion

Submission date 30/09/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/11/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-2-ways-to-treat-a-build-up-of-fluid-around-the-lung-optimum#undefined>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 19615

Study information

Scientific Title

Randomised controlled trial comparing outpatient management of malignant pleural effusion via an indwelling pleural catheter and talc pleurodesis versus standard inpatient management in improving health related quality of life

Acronym

OPTIMUM

Study objectives

The aim of the study is to investigate whether a better health related quality of life can be achieved with an indwelling pleural catheter and talc pleurodesis in managing malignant pleural effusion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First Medical Research Ethics Committee, 22/06/2015, ref: 15/LO/1018

Study design

Single-centre randomized parallel trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Cancer; Subtopic: Lung Cancer; Disease: Lung (non-small cell)

Interventions

Participants are randomly allocated into two groups.

Standard care arm: Participants undergo ultrasound guided 12F seldinger chest drain insertion and care as per the British Thoracic Society Guidelines. They will remain as an inpatient following chest drain insertion for drainage and instillation of talc pleurodesis. They will then undergo follow up at Day 7, 14, 30, 60 , 90 with ultrasound, chest X-ray and quality of life and symptom questionnaires

Pleural catheter arm: Participants undergo ultrasound guided insertion of an indwelling pleural catheter. They will then be discharged and brought for follow up to assess for trapped lung. In the absence of trapped lung, patients will undergo talc pleurodesis on Day 4 with a view to drain removal on day 14. Patients will have follow up on day 30,60 and 90.

Intervention Type

Procedure/Surgery

Primary outcome measure

Health-related quality of life, measured using the EORTC QLQ-C30 questionnaire at baseline, 7, 14 and 30 days

Secondary outcome measures

1. Health-related quality of life, measured using the EORTC QLQ-C30 questionnaire at 60 and 90 days
2. Pleurodesis failure rate, measured using chest X-rays at baseline, 1, between 2-5, 7, 14, 30, 60 and 90 days
3. Improvement in symptoms of pain and breathlessness, measured using the visual analogue scale (VAS) and MRC dyspnea score at baseline, 7, 14, 30, 60 and 90 days
4. Complication rate

Overall study start date

29/07/2015

Completion date

27/01/2020

Eligibility

Key inclusion criteria

1. Age 18 years or over
2. Diagnosis of malignant pleural effusion
3. WHO performance status 2 or less unless performance status is impaired by presence of effusion and likely to significantly improve with drainage
4. Expected survival greater than 3 months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 142; UK Sample Size: 142

Total final enrolment

142

Key exclusion criteria

1. Aged less than 18 years old
2. Pregnant or lactating
3. Known allergy to Talc or Lignocaine
4. Lack of symptomatic relief from effusion drainage
5. At least twice weekly drainage cannot be undertaken
6. Lymphoma or small cell carcinoma except*:
 - 6.1. Failure of chemotherapy
 - 6.2. Deemed for palliative management
7. Non malignant effusions
8. Loculated pleural effusion
9. Unable to provide written informed consent to trial participation

*Lymphoma and small cell carcinoma are particularly sensitive to treatment with chemotherapeutic agents. If patients have undergone chemotherapy with no treatment response or deemed not for chemotherapy and for palliative management then they will be suitable for inclusion in the study. Liason with the patient's oncologist or MDT discussion will be required to ascertain this.

Date of first enrolment

29/07/2015

Date of final enrolment

27/10/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Thomas's Hospital

249 Westminster Bridge Road

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Guy's & St Thomas' NHS Foundation Trust

Sponsor details

Department of Respiratory Medicine

First Floor Lambeth Wing

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England

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Industry

Funder Name

CareFusion Corporation

Results and Publications

Publication and dissemination plan

Publication in a peer-reviewed journal.

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The IPD from this trial will not be made available as the investigators do not have approval from their regional ethics committee to make this information available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/10/2016		Yes	No
HRA research summary			28/06/2023	No	No
Results article		23/11/2023	24/11/2023	Yes	No