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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

Registration date
30/09/2015

Overall study status
Completed

Last Edited
24/11/2023

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
St Thomas's Hospital
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Sponsor information

Organisation
Guy's & St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
CareFusion Corporation

Results and Publications

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?
Results article		23/11/2023	24/11/2023	Yes	No
Protocol article	protocol	18/10/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes