

The efficacy of sonographic and biological pleurodesis indicators of malignant pleural effusion (SIMPLE)

Submission date 10/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/06/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-using-ultrasound-and-biomarkers-in-treatment-for-pleural-effusion-simple>

Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number

CPMS 20343

Study information

Scientific Title

The efficacy of Sonographic and biological pleurodesis indicators of Malignant Pleural Effusion (SIMPLE) -- a randomised trial

Acronym

SIMPLE

Study objectives

The aim of this trial is to:

1. Establish if a novel radiological investigation (thoracic ultrasound) can improve quality and efficacy of care for MPE patients undergoing talc pleurodesis
2. Establish a biobank of prospectively collected biological samples and radiology in patients undergoing talc pleurodesis, linked to robust outcome data, to investigate factors associated with pleurodesis "success" and redefine the current understanding in a patient centred model

Ethics approval required

Old ethics approval format

Ethics approval(s)

12/11/2015, ref: 15/SC/0600

Study design

Multi-centre randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malignant pleural effusion

Interventions

Participants are randomly allocated to one of two groups:

Intervention group: Participants receive thoracic ultrasound imaging before and post talc administration.

Control group: Participants receive talc pleurodesis with no thoracic ultrasound imaging.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Length of hospital stay (in days) during the initial hospitalisation

Key secondary outcome(s)

1. Mortality rate is recorded at 12 months
2. Number of days in hospital post-randomisation with drain in situ

3. Patient reported dyspnea/chest pain post-randomisation is measured through daily assessments for 7 days and then weekly for 4 weeks
4. Patient reported quality of life is measured using the EQ-5D-5L questionnaire at baseline, 1 and 3 months
5. Pleurodesis success is determined at 1 and 3 months
6. Use of healthcare resources and costs using utilisation logs is measured as discharge, 1 and 3 months

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Clinically confident diagnosis of MPE requiring pleurodesis defined as any of the following (more than one can be included):
 - 1.1. Histocytologically proven MPE
 - 1.2. Thoracic CT evidence of pleural malignancy
 - 1.3. Otherwise unexplained exudative effusion in the context of clinically proven cancer elsewhere
2. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

313

Key exclusion criteria

1. Aged under 18 years
2. Poor prognosis (pleurodesis not offered in normal practice)
3. Irreversible contra-indication to drain insertion

Date of first enrolment

14/12/2015

Date of final enrolment

30/09/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Oxford

Respiratory Medicine Unit

NDM Research Building

Nuffield Department of Medicine

Old Road Campus

Oxford

United Kingdom

OX3 7FZ

Sponsor information**Organisation**

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/10/2021	12/10/2021	Yes	No
Protocol article	protocol	20/11/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			04/06/2024	No	Yes