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

Submission date 10/02/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/02/2016	**Overall study status** Completed	
Last Edited 04/06/2024	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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

Secondary outcome measures
1. Mortality rate is recorded at 12 months
2. Number of days in hospital post-randomisation with drain in situ
3. Patient reported dysponea/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

Overall study start date
14/12/2015

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

Age group
Adult

Sex
Both

Target number of participants

Planned Sample Size: 344; UK Sample Size: 344

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
England

United Kingdom

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

Sponsor details
Research Services
Clinical Trials and Research Governance
Headley Way
Headington
Oxford
England

United Kingdom
OX3 9DU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/04/2020

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?

Protocol article	protocol	20/11/2017		Yes	No
Results article		08/10/2021	12/10/2021	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			04/06/2024	No	Yes