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

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

#### Contact name

Prof Ioannis Psallidas

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#### Contact details

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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?

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