

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

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

### Contact name

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## Additional identifiers

### Central Portfolio Management System (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

## Primary study design

Interventional

## Study design

Multi-centre randomized controlled trial

## 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 dyspnoea/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? |
|---------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | protocol | 08/10/2021   | 12/10/2021 | Yes            | No              |
| <a href="#">Protocol article</a>      |          | 20/11/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a>  |          |              | 28/06/2023 | No             | No              |
| <a href="#">Plain English results</a> |          |              | 04/06/2024 | No             | Yes             |