

# Prospective randomised controlled trial of video assisted cytoreductive pleurectomy compared to talc pleurodesis in patients with suspected or proven mesothelioma

<b>Submission date</b> 12/02/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-for-fluid-around-the-lung-caused-by-mesothelioma>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Vikki Hughes

### Contact details

Papworth Hospital  
Papworth Everard  
Cambridge  
United Kingdom  
CB23 3RE  
+44 (0)148 036 4821  
[victoria.hughes@papworth.nhs.uk](mailto:victoria.hughes@papworth.nhs.uk)

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00821860

### Protocol serial number

2.0

# Study information

## Scientific Title

Prospective randomised controlled trial of video assisted cytoreductive pleurectomy compared to talc pleurodesis in patients with suspected or proven mesothelioma

## Acronym

MesoVATS

## Study objectives

The MesoVATS trial is a randomised phase III study comparing surgical pleurectomy and palliative pleurodesis to determine which is the better at preventing fluid recurrence.

On 15/02/2011 the overall trial end date was changed from 31/12/2009 to 30/06/2012.

On 25/01/2012 the overall trial end date was changed from 30/06/2012 to 30/12/2012.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee (LREC) (ref: H02/809)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Mesothelioma

## Interventions

Group 1 - pleurodesis:

A procedure in which a chest tube is placed between the lungs and chest wall, and fluid is drained from the intrapleural space. A talc substance will then be administered through the tube. The chest tube will most likely stay in place for a few days following this procedure, and patients will remain hospitalised for about a week.

Group 2 - Video-Assisted Thoracoscopic (VATS) pleurectomy:

A chest tube will be inserted between the lungs and chest wall, and fluid will be drained. Surgery will then be performed to remove the pleural membrane. This is done under general anesthetic, and the chest tube will remain in place for up to 10 days. Patients will remain hospitalised for up to two weeks.

## Intervention Type

Procedure/Surgery

**Primary outcome(s)**

1. Survival at 1 year
2. Control of effusion
3. Quality of life

**Key secondary outcome(s))**

No secondary outcome measures

**Completion date**

30/12/2012

## Eligibility

**Key inclusion criteria**

1. Proven or suspected mesothelioma
2. Pleural tumour with associated pleural effusion
3. Fit enough for Video-Assisted Thoracoscopic (VATS) pleurectomy
4. Patients who have had a previous malignancy for which they are no longer receiving treatment, provided they have a confirmed diagnosis of mesothelioma

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients who are unfit for a VATS procedure
2. Patients who have had previous attempted pleurodesis
3. Patients without a pleural effusion

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

06/01/2012

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Papworth Hospital**  
Cambridge  
United Kingdom  
CB23 3RE

## Sponsor information

**Organisation**  
Papworth Hospital NHS Foundation Trust (UK)

**ROR**  
<https://ror.org/01qbebb31>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
British United Provident Association (BUPA) (UK)

## Results and Publications

**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?
<a href="#">Results article</a>	results	20/09/2014		Yes	No