

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00821860

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/09/2003

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

Age group

Adult

Sex

Both

Target number of participants

196

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

England

United Kingdom

Study participating centre

Papworth Hospital

Cambridge

United Kingdom

CB23 3RE

Sponsor information

Organisation

Papworth Hospital NHS Foundation Trust (UK)

Sponsor details

Papworth Everard

Cambridge

England

United Kingdom

CB3 8RE

Sponsor type

Hospital/treatment centre

Website

<http://www.papworthpeople.com/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

British United Provident Association (BUPA) (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	results	20/09/2014		Yes	No