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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

Registration date
16/03/2004

Overall study status
Completed

Last Edited
13/02/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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