ISRCTN12709516 https://doi.org/10.1186/ISRCTN12709516

# Debulking surgery and hyperthermic chemotherapy for pleural mesothelioma: a pilot study.

**Submission date**
18/01/2017

**Recruitment status**
No longer recruiting

**Registration date**
23/01/2017

**Overall study status**
Completed

**Last Edited**
02/01/2024

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Pleural mesothelioma is a cancer found in the lining of the lungs, usually as a result of contact with asbestos (a building material that was used in construction that has been banned). The symptoms include chest pain, cough, tiredness, fever (high temperature), weight loss and trouble breathing. There is no cure for pleural mesothelioma but the symptoms can be treated, usually through surgery removing fluid that builds up in the lungs. Due to new technology, surgeons now have more options in treating this cancer in order to improve the quality of life and survival rates of patients. Video assisted thoracoscopic surgery (VATS) is a type of surgery that uses a video camera to see inside the chest which has made it possible to access the lungs without having to cut the entire chest open. This is a less dangerous type of procedure that more patients can have. In Italy, there are areas in Catania that has high levels of patients with mesothelioma, presenting challenges to surgeons but with opportunity to explore new procedures. This studies aims to examine and compare new types of VATS to remove cancer will improve the quality of life of the patients.

Who can participate?
Adults with mesothelioma who are able to undergo a VATS surgery.

What does the study involve?
Participants are allocated to groups, based on which clinic they go to. Participants in both groups will have excess liquid in the chest and lungs drained.
Those in the first group will have a debulking surgery done as well as a hyperthermic intraoperative intrathoracic chemotherapy (HITHOC) procedure. This involves having surgery to remove as much as the cancer in the chest as possible without completely removing the lungs lining, whilst using a high amount of chemotherapy (anti-cancer drugs) that is warmed and left in the chest for a period of time.
The second group will receive talc pleurodesis, which involves a chemical inserted into the chest area that prevents liquid from building up in that area. At the beginning of the study and at three, six and 12 months participants complete a questionnaire to assess their quality of life and medical records are reviewed to look for complications and length of hospital stay.

What are the possible benefits and risks of participating?
A possible benefit is to help improve the symptoms of mesothelioma by reducing hospital death rates and improving short and long term survival. There are no major risks of participating.

Where is the study run from?
1. Policlinico University Hospital, University of Catania (Italy)
2. Morgani Institute (Italy)
3. Policlinico Giaccone, University of Palermo (Italy)

When is the study starting and how long is it expected to run for?
June 2014 to December 2017

Who is funding the study?
University of Catania FIR (Italy)

Who is the main contact?
Professor Marcello Migliore
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# Contact information

### Type(s)
Public

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

DFB4A9

# Study information

### Scientific Title
Prospective randomised controlled trial of video-assisted thoracoscopic Cytoreductive Pleurectomy (VATS-CP) with Hyperthermic Intraoperative Chemotherapy (HIC) compared to talc pleurodesis (TP) in patients with Malignant pleural Mesothelioma (MPM): a pilot study

### Acronym
CPHICMM

### Study objectives
This study will test if a more active management of mesothelioma using cytoreductive surgery will improve the quality of life and overall survival of patients, by studying the effect of video-assisted thoracoscopic surgery (VATS) pleurectomy decortication with intraoperative hyperthermic chemotherapy.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
University Research Area-Financial Research Committee, December 4th 2015, ref: DFB4A9

### Study design
Multi-centre two-arm randomized parallel study

### Primary study design
Interventional

### Secondary study design
Randomised parallel trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
No participant information sheet available

### Health condition(s) or problem(s) studied
Malignant pleural mesothelioma

### Interventions
Participants receive either debulking and hyperthermic intraoperative intrathoracic chemotherapy (HITHOC) or talc pleurodesis depending on which trial participating centre they attend. This is determined based on the expertise at each of the participating centres.

All patients who arrive at the University Catania undergo Debulking and HITHOC.
All patients who arrive at the University of Palermo and Morgagni Institute undergo Talc pleurodesis. There is no interaction between the centres.

The HITHOC arm:
This group will undergo a debulking and HITHOC procedures surgically. Debulking procedure is a less intensive than a pleuro-pneumonectomy (where all of the pleura lining of the chest wall and lung are removed), where as much as the mesothelioma is removed as possible. It is also known as a partial pleurectomy. HITHOC is is a concentrated dose of chemotherapy, or a warmed anti-cancer drugs are infused and circulated in the are for a short period of time. Pleural effusion is also done at the beginning of the operation to drain excess fluid from the chest. All operated randomized patients will have 100mls of pleural effusion taken at the beginning of the operation, at the end of the operation and at the end of the HITHOC.

The talc pleurodesis arm:
Participants in this arm will receive a chemical form of pleurodesis which removes the entire pleural space so that excess fluid cannot build up in that area. Talc is the most effective sclerosant in malignant pleural effusion. Pleural effusion is done so that the area is drained to dryness. Talc will be inserted under direct vision. A drain will be kept on suction for 48-96 hours until the drainage is less than 150ml/24 hours in order to drain the pleural effusion.

Participants are followed up at 3, 6 and 12 months.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Participants quality of life will be assessed by the Symptoms and Quality of Life: European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire at baseline and at 3, 6 and 12 months.

### Secondary outcome measures
1. Survival rates of participants will be measured using personal interview or phone calls throughout the whole study period
2. Length of hospital stay will be assessed by case report forms throughout study period during the hospitalisation
3. Complications from the procedure will be assessed by case report forms (CRF) at baseline, 3, 6 and 12 months
4. Recurrence of pleural effusion will be assessed by plain chest radiograph at 3, 6 and 12 months

### Overall study start date
01/06/2014

### Completion date
31/12/2017

## Eligibility

### Key inclusion criteria
1. Proven or suspected mesothelioma attending the Policlinico mesothelioma outpatient clinic
2. Patients that have given verbal and written consent to participant

3. Patients with pleural tumour and with associated pleural effusion that are fit enough for VATS pleurectomy/decortication
4. Patients attending Morgani clinic and University of Palermo that are undergoing talc pleurodesis

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
12 patients per group

### Total final enrolment
27

### Key exclusion criteria
1. Unfit for a VATS procedure
2. Previously attempted pleurodesis
3. Without a pleural effusion

### Date of first enrolment
01/07/2014

### Date of final enrolment
30/07/2017

## Locations

### Countries of recruitment
Italy

### Study participating centre
**Minimally Invasive Thoracic Surgery and New Technology, Policlinico University Hospital, University of Catania**
Via S. Sofia 78
Catania
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95124

### Study participating centre
**Thoracic Surgery, Morgani Institute**
Via del Bosco

105
Catania
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**Study participating centre**
**Thoracic Surgery, Policlinico Giaccone, University of Palermo**
Via del Vespro
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# Sponsor information

**Organisation**
University of Catania

**Sponsor details**
Piazza Università, 2,
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95124

**Sponsor type**
Government

**ROR**
https://ror.org/03a64bh57

# Funder(s)

**Funder type**
University/education

**Funder Name**
University of Catania FIR

# Results and Publications

## Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

## Intention to publish date
31/12/2018

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Marcello Migliore mmiglior@hotmail.com

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Preprint results | Preprint results | 28/11/2021 | 10/08/2022 | No | No |
| Results article | | 25/05/2023 | 02/01/2024 | Yes | No |