

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

Submission date 18/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/01/2024	Condition category Cancer	<input type="checkbox"/> 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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Protocol serial number

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

Study type(s)

Treatment

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 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Italy

95124

Study participating centre

Thoracic Surgery, Morgani Institute

Via del Bosco

105

Catania

Italy

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Study participating centre

Thoracic Surgery, Policlinico Giaccone, University of Palermo

Via del Vespro

129

Palermo

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04354

Sponsor information

Organisation

University of Catania

ROR

<https://ror.org/03a64bh57>

Funder(s)

Funder type

University/education

Funder Name

University of Catania FIR

Results and Publications

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?
Results article		25/05/2023	02/01/2024	Yes	No
Preprint results	Preprint results	28/11/2021	10/08/2022	No	No