Palliative pleurectomy / decortication in patients with malignant pleural mesothelioma after standard chemotherapy. A multicenter, randomised, phase III study.

Published: 10-02-2009
Last updated: 06-05-2024

Primary objective is to investigate whether palliative pleurectomy / decortication after 4-6 courses of standard chemotherapy with cisplatin and pemetrexed will lead to a doubling of the overall survival compared to a control group which will...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mesotheliomas
Study type	Interventional

Summary

ID

NL-OMON33742

Source
ToetsingOnline

Brief title
Palliative pleurectomy in pleural mesothelioma after standard chemotherapy

Condition

- Mesotheliomas
- Pleural disorders
- Breast therapeutic procedures

Synonym
mesothelioom

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KWF CKTO vergoeding

Intervention

Keyword: decortication, mesothelioma, pleurectomy, randomised trial

Outcome measures

Primary outcome

Overall survival

Secondary outcome

Pain score (VAS)

Dyspnea (VAS)

Quality of Life

Time to disease progession

Improvement in lung function

Study description

Background summary

Pleural mesothelioma is a malignant disease of the pleura. The disease usually spreads loco-regionally with in rare cases distant metastases late in the course of the disease. As a result, patients suffer often from heavy pain and dyspnea due to thoracic wall ingrowth, shrinking of the affected hemithorax and / or pleural fluid. Consequently, patients usually die as a result of loco-regional complications and not as a result of distant metastatic disease.

The question is whether a debulking procedure with removal of the majority of the tumor mass and the affected pleura by palliative pleurectomy / decortication after standard chemotherapy consisting of cisplatin and

pemetrexed might lead to an improvement in overall survival and a decrease in pain, dyspnea and an improvement in quality of life as a result of a better expansion of the affected lung and less ingrowth in the thoracic wall and other surrounding structures.

This hypothesis is supported by evidence from non-randomised retrospective studies suggesting that palliative pleurectomy / decortication may indeed lead to an improvement (doubling) of the overall survival

Study objective

Primary objective is to investigate whether palliative pleurectomy / decortication after 4-6 courses of standard chemotherapy with cisplatin and pemetrexed will lead to a doubling of the overall survival compared to a control group which will receive best supportice care

Secondary obejectives are to investigate whether palliative pleuractomy will lead to improvement in quality of life with less pain and dyspnea compared to the control arm which will receive best supportive care

Study design

This a prospective randomised controlled trial (phase III study) comparing palliative pleurectomy-decortication with best supportive care without disease progression after 4-6 courses cisplatin-pemetrexed

Intervention

Pleurectomy-decortication will be performed preferably as a minimal invasive procudure (Video-assisted thoracoscopy). If this is impossible an open thoracotomy will be performed. Primary objective is to remove as much as possible tumor mass (debulking procedure) without removing the lung. The extent of resection will be scored for predefined regions of the thoracic cavity and the removed tumor mass will be weighted according to palliative surgery for ovarium cancer. Prostetic reconstruction of the pericardium or diaphragm is allowed if needed. The operation should take place within 11 weeks after the first day of the last chemotherapy course.

Study burden and risks

Possible complication of a video-assisted or open thoracotomy for pleuractomy-decortication are

- post-operative pain
- pneumonia

-persistent air leak and chest tube
-empyema
-cardiac arrythmias

Is is expected that patients will stay on average for 5 days in the hospital

Based on previous studies with pleurectomy-decortication in mesothelioma patients, the operative mortality is less than 5 %, comparable with other operative pulmonary procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Fit enough to undergo pleurectomy / decortication after 4-6 courses cisplatinum-

pemetrexed.;Histological proven malignant pleural mesothelioma;Any T, except extension to contralateral pleura, abdomen, or invasion of the myocardium, any N any M.;Performance status WHO 0 or 1;Weight loss < 10% in last 3 months;Standard chemotherapy with pemetrexed and cisplatin which must have resulted in CR, PR or SD;No prior chest radiotherapy ;No prior or other malignancies, except if longer than 5 yrs ago and adequately treated;No uncontrolled infection

Exclusion criteria

Objective progressive disease after 4-6 cycles of standard chemotherapy with cisplatin and pemetrexed.;Ongoing grade >=2 toxicity (CTC v 3.0) due to prior standard chemotherapy other than alopecia, polyneuropathy and tinnitus.;Weight loss > 10% in last 3 months before randomisation;Prior chest radiotherapy (except radiotherapy on chest tube port).;Prior or current other malignancies, except if longer than 5 years ago and adequately treated.;No other severe medical illness, including psychosis. ;Any concurrent anti-cancer treatment or use of investigational drugs. Palliative radiotherapy is allowed.;Uncontrolled infections

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2009
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	10-02-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL25044.078.08