Tumor cells in pleural effusion and peripheral blood of malignant pleural mesothelioma patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mesotheliomas
Study type	Observational non invasive

Summary

ID

NL-OMON40425

Source
ToetsingOnline

Brief title
MESOPA

Condition

- Mesotheliomas

Synonym
maligant pleural mesothelioma, malignant mesothelioma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: circulating endothelial cells, circulating tumor cells, malignant pleural mesothelioma, pleural effusion tumor cells

Outcome measures

Primary outcome

Verdict of pleural effusion analysis (negative for MPM, suspicious for MPM or

positive for MPM) by PTC enumeration versus cytological analysis.

Secondary outcome

- Number of CTCs

- Number of CECs

- Number of immune cells

- Overall survival

Study description

Background summary

Malignant pleural mesothelioma (MPM) is an aggressive and treatment-resistant neoplasm that is often asbestosis-induced. Patients suffering from MPM often present with pleural effusions. Currently, no biomarker is available with an accuracy which is clinically acceptable to either confirm or exclude the diagnosis malignant mesothelioma, based on pleural effusion cytology. Therefore, thoracoscopy is still the golden standard for diagnosing MPM. A thoracoscopy is an invasive procedure associated with morbidity (amongst which hospitalisation, pain, cardiac rhythm problems) and even with adequate tissue it can be difficult to conclusively identify MPM. We hypothesize that the use of a modified CellSearch enrichment method will specifically detect MPM tumor cells in the pleural effusion of patients with MPM. By using this approach, we aim to increase the sensitivity of fluid cytology of pleural effusion in MPM thereby contributing to a better diagnosis of MPM and hopefully a better outcome for patients.

Study objective

Main objective is to investigate whether the use of a modified CellSearch enrichment for the enumeration of pleural effusion tumor cells (PTCs) is able to increase sensitivity of pleural effusion evaluation in MPM, as compared to standard cytological analysis by the pathologist. Secondary objectives include the investigation of the presence of circulating tumor cells (CTCs) in MPM patients and its correlation with the presence of PTCs, the indisputable confirmation that PTCs in patients with MPM indeed represent MPM cells, to investigate whether there are tumor derived circulating endothelial cells present in patients with MPM and to investigate the presence of immune cells (e.g. regulatory T-cells and MDSC) and cytokines in MPM patients.

Study design

Prospective, non-randomized controlled trial

Intervention

In all patients, except in the control patients, 3x10 mL of peripheral blood will be drawn for circulating tumor cell (CTC), circulating endothelial cell (CEC) and immune cell analysis.

Study burden and risks

Of all patients, 3x10 mL blood will be drawn for CTC, CEC and immune cell analysis. In addition, pleural effusion material and, if applicable, MPM tissue will be collected if there is residual material (which is usually the case, since mesothelioma patients often present with large amounts of pleural effusion fluid).

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

- Age ><=18 years
- Patient requiring a pleural drainage or VATS as a part of standard care
- High clinical suspicion of the presence of pleural effusion
- Written informed consent

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2014
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

ID: 20403
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47437.078.14
OMON	NL-OMON20403