# 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

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

## Ethics review

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| 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: NTR
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL47437.078.14 |
| OMON | NL-OMON20403 |