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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20403

Source
Nationaal Trial Register

Brief title
MESOPA

Health condition

Malignant pleural mesothelioma
Mesothelioma
Pleural effusion tumor cells
Circulating tumor cells
Circulating endothelial cells
Asbestkanker
Maligne pleuraal mesothelioom

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute
Source(s) of monetary or material Support: Erasmus MC Cancer Institute

Intervention

Outcome measures

Primary outcome

To investigate the use of a modified CellSearch enrichment for the enumeration of pleural effusion tumor cells (PTCs) to increase sensitivity of pleural effusion evaluation in malignant pleural mesothelioma (MPM) as compared to standard cytological analysis by the pathologist

Secondary outcome

- To investigate the presence of circulating tumor cells (CTCs) in MPM patients and its correlation with the presence of PTCs

- To indisputably confirm that PTCs in patients with MPM indeed represent MPM cells

- To investigate the presence of tumor-derived circulating endothelial cells in MPM patients

- To develop a flow cytometric method for the enumeration of PTCs in MPM patients

- To investigate whether the number of PTCs, CTCs, CECs or immune cells is a prognostic marker for overall survival in MPM patients

- To explore the occurrence of immune suppressive cells (e.g. regulatory T-cells and MDSC) and associated cytokines in the peripheral blood of MPM patients and their correlation with the occurrence of CTC

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 that 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 and peripheral blood of patients with MPM. By using this approach,
we aim to increase the sensitivity of fluid cytology of pleural effusion in MPM as well as to explore the use of circulating biomarkers in peripheral blood of MPM patients, thereby contributing to a better

diagnosis of MPM and hopefully a better outcome for patients.

Study objective

We hypothesize that the use of a modified CellSearch enrichment method will specifically detect MPM tumor cells in the pleural effusion and peripheral blood of patients with MPM

Study design

Baseline: blood draw and pleural effusion punction

Follow-up: follow-up of overall survival up to 2.5 year following baseline

Intervention

1) blood collection for circulating tumor cell enumeration, circulating endothelial cell enumeration and immune cell analysis

2) pleural effusion collection for pleural effusion tumor cell analysis

(NB these are not formal interventions, since they are being performed as a part of standard clinical practice)

Contacts

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Eligibility criteria

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:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40425
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4452
NTR-old	NTR4575
CCMO	NL47437.078.14
OMON	NL-OMON40425

Study results