

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

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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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20403

Bron

Nationaal Trial Register

Verkorte titel

MESOPA

Aandoening

Malignant pleural mesothelioma

Mesothelioma

Pleural effusion tumor cells

Circulating tumor cells

Circulating endothelial cells

Asbestkanker

Maligne pleuraal mesothelioom

Ondersteuning

Primaire sponsor: Erasmus MC Cancer Institute

Overige ondersteuning: Erasmus MC Cancer Institute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Baseline: blood draw and pleural effusion puncture

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

Onderzoeksproduct en/of interventie

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)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age $\geq$ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	02-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40425

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten