Voorspellende waarde van soluble mesothelin-related peptide, CEA, Cyfra 21-1 and CA 125 bij patiënten met pleuravocht.

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Establishing the cause of pleural disease often is a great challenge. Definitive diagnosis of pleural disease needs histological confirmation in most cases. Clinical suspicion of malignancy often indicates prompt use of invasive procedures like...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20116

Bron
NTR

Aandoening

pleural effusion, tumour markers, mesothelin.
pleuravocht, tumormarkers, mesotheline

Ondersteuning

Primaire sponsor: Maatschap longziekten MST Enschede
Maatschap longziekten ZGT Almelo
Overige ondersteuning: Maatschap longziekten MST Enschede
Maatschap longziekten ZGT Almelo

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To test the diagnostic capacity for malignancy in pleural fluid of the tumour markers SMRP, CEA, Cyfra 21-1 and Ca 125 by patients presenting with pleural fluid without any known or suspected cause.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Establishing the cause of pleural disease often is a great challenge. Definitive diagnosis of pleural disease needs histological confirmation in most cases. Clinical suspicion of malignancy often indicates prompt use of invasive procedures like thoracoscopy. In the case of elderly and or disabled patients it is often worthwhile to have clinical arguments to decide whether thoracoscopy should be part of the diagnostic procedures. Therefore additional information about the underlying disease causing pleural abnormalities is often valuable.

Study title:

The predictive value of tumour marker in serum and pleural fluid.

Main investigators:

Dr J.H. Schouwink, mevr dr. Ir. L. Mulder, H. Sinnighe Damste, O. Akkerman.

Purpose of the study:

Primary, to test the diagnostic capacity of the tumour markers SMRP, CEA, Cyfra 21-1 and Ca 125 differentiating malignant from benign disease. Secondly, the prognostic value of the same markers in malignant pleural disease.

Population:

Patients, aged over 18 years, with pleural fluid at presentation in the outpatient clinic. The pleural fluid needs further analysis. Excluded will be all patients with a known cause of the pleural fluid. Patients with a pleural empyema (clinically or radiologically) or all patients with a treated malignancy in the 2 years before presentation are excluded.

Study design:

This study is a multi-centre cohort trial in patients with pleural effusion without any known cause or evidentially expected cause.

All patients will have thoracocentesis at presentation and if possible after 3 months. We will also collect serum at the same time. Also other baseline characteristics with a proven prognostic value for MPM will be collected, (i.e. Karnofsky score, pain at presentation, thrombocyte count).

Outcome measures:

Primary, to test the diagnostic capacity for malignancy in pleural fluid of the tumour markers SMRP, CEA, Cyfra 21-1 and Ca 125 by patients presenting with pleural fluid without any known or suspected cause. Secondly, the prognostic value of the same markers in malignant pleural fluid.

Doel van het onderzoek

Establishing the cause of pleural disease often is a great challenge. Definitive diagnosis of pleural disease needs histological confirmation in most cases. Clinical suspicion of malignancy often indicates prompt use of invasive procedures like thoracoscopy. In the case of elderly and or disabled patients it is often worthwhile to have clinical arguments to decide whether thoracoscopy should be part of the diagnostic procedures. Therefore additional information about the underlying disease causing pleural abnormalities is often valuable. It might be usefull to add the predictive value of tumour markers in serum and pleural fluid in this diagnostic process.

Onderzoeksopzet

1. Diagnostic capacity, timepoint: 0 and 3 months;

2. Prognostic capacity, timepoint: 1 1/2 year.

Onderzoeksproduct en/of interventie

1. Thoracentesis;

2. Venapuncture.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pleural fluid;

2. Age over 18 years;

3. Clinical indication for analysing pleural fluid.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known cause of the pleural fluid;

2. Clinical and/or radiological suspicion for pleural empyema;

3. Malignancy in the 2 years before presentation.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2010
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2235
NTR-old	NTR2361
Ander register	METC MST Enschede : P10-11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A