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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20116

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Maatschap longziekten MST Enschede
Maatschap longziekten ZGT Almelo
Source(s) of monetary or material Support: Maatschap longziekten MST Enschede
Maatschap longziekten ZGT Almelo

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The prognostic capacity of the same markers in malignant pleural disease.

Study description

Background summary

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.

Study objective

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.

Study design

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

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

Intervention

1. Thoracentesis;

2. Venapuncture.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pleural fluid;

2. Age over 18 years;

3. Clinical indication for analysing pleural fluid.

Exclusion criteria

1. Known cause of the pleural fluid;

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

3. Malignancy in the 2 years before presentation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2010
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2235
NTR-old	NTR2361

Register	ID
Other	METC MST Enschede : P10-11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A