A randomized trial comparing longstanding indwelling pleural catheters with pleurodesis as a frontline treatment for malignant pleural effusion.

Published: 18-08-2010
Last updated: 10-08-2024

To compare the palliative efficacy of talc pleurodesis with the indwelling catheter

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON34219

Source
ToetsingOnline

Brief title
IPC vs talc pleurodesis

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
malignant pleural effusion

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: aanvraag is ingediend bij het KWF (CKS);nog niet gehonoreerd

Intervention

Keyword: IPC, malignant pleural effusion, talc pleurodesis

Outcome measures

Primary outcome

Primary endpoint

• Patient reported dyspnoea at 4 to 6 weeks after the intervention, assessed by the Modified Borg scale

Secondary outcome

Secondary endpoints:

• The number of emergency presentations or presentations at the outdoor clinic for reasons of symptomatic MPE after completion of the treatment

• The number of interventions for MPE after completion of the MPE treatment

• The overall time of hospitalization because of MPE

• Patient reported dyspnoea and thoracic pain, directly following catheter placement, and 3 and 6 months after the randomization

• Quality of Life

• The treatment outcome at 1, 3 and 6 months

• Overall treatment costs in relation to MPE

• Adverse events

• Overall survival

• Detection of prognostic markers for the outcome of the intervention

• Development of a clinical decision rule for treatment of MPE

Study description

Background summary

Patients with malignant pleural effusion (MPE) have a dismal prognosis. Pleural fluid drainage is often necessary because of the symptoms. Talc pleurodesis has become the method of choice to prevent recurrences. Recent intention-to-treat analysis showed that outcome of pleurodesis is poor. There are no reliable clinical factors that can be used to predict treatment outcome upfront. Indwelling catheters form an alternative palliative intervention and provide us with the opportunity to evacuate the pleural effusion on demand at home with a minimal of hospitalizations.

Study objective

To compare the palliative efficacy of talc pleurodesis with the indwelling catheter

Study design

Prospective multicenter randomized trial

Intervention

The first treatment for all patients is the therapeutic thoracentesis.
Patients with recurrence of symptomatic MPE and fulfilling in- and exclusion criteria are candidates for the randomized trial. Patients can be randomized for the standaard arm (talc pleurodesis) or the experimental arm (indwelling pleural catheter).
Patient, randomized for the standaard arm, pleurodesis will be performed according to the Dutch consensus guideline [4] and all patients will be hospitalized for intercostal catheter placement.
Patients, randomized for the experimental arm, an IPC will be placed, preferably under ultrasound guidance. Hospitalization is not warranted.

Study burden and risks

not applicable

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

symptomatic pleural effusion
any histologically or cytologically proven malignancy
written informed consent
recurrence of pleural effusion within 6 months after last therapeutic thoracentesis
* written informed consent (part 2)

Exclusion criteria

other causes of pleural effusion than malignancy
previous chemical or surgical pleurodesis
impaired immunity: leucopenia <2.0 x 109/L, high dose corticosteriods (>=1mg/kg)
thrombocytopenia (< 50 x 109/L)

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	18-08-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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: 21466
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL32135.031.10