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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21466

Source
NTR

Brief title
IPC vs talc pleurodesis

Health condition

Malignant pleural effusion
IPC (indwelling pleural catheter)
Talc pleurodesis

Maligne pleuravocht
Verblijfsdrain
Talk pleurodese

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoekziekenhuis (NKI-AVL), Amsterdam, The Netherlands
Source(s) of monetary or material Support: not yet known

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Number of emergency presentations at the outpatient clinic for reasons of symptomatic MPE after completion of the treatment;

2. Number of interventions for MPE after completion of the MPE treatment;

3. The overall time of hospitalization because of MPE;

4. Patient reported dyspnoea and thoracic pain, directly following catheter placement and 3 and 6 months after randomization;

5. Quality of Life;

6. The treatment outcome at 1,3 and 6 months;

7. Overall treatment costs in relation to MPE;

8. Adverse Events;

9. Overall survival;

10. Detection of prognostic markers for the outcome of the intervention;

11. Development of a clinical decision rule for treatment of MPE.

Study description

Background summary

Consecutive 120 patients with symptomatic MPE will be registered in part 1 (thoracentesis) of the study. 80 patients (of the 120) with recurrent symptomatic MPE will be asked to participate in a randomized trial comparing the standard talc pleurodesis (arm A) with the experimental treatment, the indwelling catheter (arm B). Primairy endpoint of the study is

the patient reported dyspnoea at 4 to 6 weeks after the intervention, assessed by the Modified Bord scale.

Study objective

The observed improvement in palliative care (dyspnoea is the most prominent symptom) in the pleurodesis group is less than the improvement in the indwelling arm.

Study design

1. First patient in 2010 Q3;

2. Final patient in 2012 Q1;

3. Data lock 2012 Q3;

4. Reporting 2013 Q1.

Intervention

1. Thoracentesis;

2. Talc pleurodesis;

3. Placement of indwelling pleural catheter.

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptomatic pleural effusion;

2. Any histologically or cytologically proven malignancy;

3. Written informed consent;

4. Recurrence of pleural effusion within 6 months after last therapeutic thoracentesis.

Exclusion criteria

1. Other causes of pleural effusion than malignancy;

2. Previous chemical or surgical pleurodesis;

3. Impaired immunity: Leucopenia <2.0 x 109/L, high dose corticosteriods (>=1 mg/kg);

4. Thrombocytopenia (<50 x 109/L).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010

Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-09-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34219
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2410
NTR-old	NTR2518
CCMO	NL32135.031.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34219

Study results

Summary results
A final report will be prepared for publication in peer reviewed journals.
Authorship will include investigators who have recruited at least 10% of the total number of evaluable patients and investigators who participated significantly to the translational research.

The authors sequence should usually reflect the input (like the number of evaluable patients enrolled) of/by the respective investigator.
Draft versions of abstracts or manuscripts must be made available to the co-authors before any presentation of results or submission for publication.