

NVALT 14 – study

Title:

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

Primary Objective:

To compare the patient reported outcome of talc pleurodesis and indwelling catheter, assessed by the Modified Borg dyspnoea Scale (MBS).

Secondary Objectives:

- To compare:
 - The number of interventions for MPE
 - The number of presentations for MPE
 - The overall time of hospitalization because of MPE
 - The symptom score of both intervention strategies (visual analogue scale (VAS) for pain and dyspnoea, baseline dyspnoea index (BDI)
 - Quality of Life (EORTC QLQ-C15-PAL)
 - The treatment outcome at 1, 3 and 6 months
 - The costs related to MPE treatment of both intervention strategies
 - Adverse events
 - Overall survival
- To develop a decision rule for treatment of MPE

Treatment arm A: Talc pleurodesis

Treatment arm B: Indwelling pleural catheter

Start date:

February 2011

Total:

120 patients will be registered in part 1 of the study and 80 patients (of the 120) will be asked to participate in a randomized trial (part 2).

Study Coördinator:

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Central Data Management:

NVALT Data Center, Amsterdam