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