

NVALT 8B study

Title:

A randomized phase III study of adjuvant chemotherapy with or without low-molecular weight heparin in completely resected Non-Small-Cell Lung Cancer patients with high-risk for recurrence: NVALT- 8B.

Primary objective:

Recurrence-free survival

Secondary objectives:

- Overall survival
- Dose intensity of subsequent cycles
- Differences in quality of life before and after chemotherapy
- Toxicity (CTC criteria version 3.0)
- Health economics

Exploratory endpoints:

Analysis of tumor and blood samples for predictive and prognostic markers.

Treatment arm 1:

Cisplatin / Pemetrexed or Cisplatin / Gemcitabine

Treatment arm 2:

Cisplatin / Pemetrexed + Nadroparin for 16 weeks
or Cisplatin / Gemcitabine + Nadroparin for 16 weeks

Start date:

November 2007

Total:

600 patients

Study Coordinators:

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Central Data management:

NVALT Data Center, Amsterdam