NVALT 8 study

Title:
A randomized phase II study of adjuvant chemotherapy with or without low-molecular weight heparin in completely resected non-small-cell lung cancer patients: NVALT- 8.

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 patients with high versus low SUVmax in the primary tumor
- Analysis of histology
- Analysis of tumor and blood samples for prognostic markers, genomics/proteomics

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:
200 patients

Study Coordinators:
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Central Data management:
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