

NVALT 8A study

Title:

A randomized phase III study of adjuvant chemotherapy in patients with completely resected Non-Small-Cell Lung Cancer and low-risk for recurrence: NVALT-8A

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)
- Health economics

Exploratory endpoints:

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

Treatment arm 1:

Observation

Treatment arm 2:

4 cycles chemotherapy

Start date:

November 2007

Total:

864 patients

Study Coordinators:

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Central Data management:

NVALT Data Center, Amsterdam