

NVALT 11 study:

Title:

Prophylactic Cranial Irradiation (PCI) versus observation in radically treated patients with stage III non-small cell lung cancer: A phase III randomized study.

Primary objective:

To determine whether PCI decreases the proportion of patients developing symptomatic brain metastases in patients with radically treated stage III NSCLC.

Secondary objectives:

To determine the time to develop neurological symptoms, the side effects and effects on the general condition of PCI with the CTCAE 3.0 scoring system, assessed by the patient, the Quality of Life, the effect of PCI on the overall survival and to find out whether PCI is cost-effective as opposed to observation in this setting. (This last part of the study will only be performed in Maastricht.)

Arm 1:

PCI: 30 Gy delivered in 10 once-daily fractions, 30 Gy delivered in 12 once-daily fractions or 36 Gy delivered in 18 once-daily fractions

Arm 2:

Observation

Start date:

September 2008

Total:

300 patients

Study Coordinators:

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Centraal Data Management:

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