NVALT 12 - study

Title:
A randomized phase II study of Paclitaxel – Carboplatin - Bevacizumab with or without Nitroglycerin patches in patients with stage IV Non – Squamous – Non - Small Cell Lung Cancer: NVALT 12

Primary Objective:
The addition of NTG patches to bevacizumab containing chemotherapy (experimental arm) improves PFS in patients with stage IV non-squamous NSCLC, compared to bevacizumab containing without NTG (control arm)

Secundary Objectives:
- Objective response rate (ORR) and disease control rate (DCR)
- Duration of response
- OS
- Safety
- Time to disease progression or death

Exploratory Objectives:
- Prediction of early response and decrease of hypoxia by [8F] FDG-PET-scan
- Investigating the effect on tumor hypoxia by [18F] HX4 or [18F] FAZA scans (selected centers)
- Evaluation of response by blood and tumor biomarkers

Treatment arm A:
Paclitaxel 200 mg/m2 d1-Carboplatin AUC 6 d1-Bevacizumab 15 mg/kg d1 every 3 weeks for 4 cycles
Bevacizumab until progression.

Treatment arm B:
Paclitaxel 200 mg/m2 d1-Carboplatin AUC 6 d1-Bevacizumab 15 mg/kg d1 every 3 weeks nitroglycerin transdermal patch delivering NTG 15 mg/24h for 5 days (d -2 till +3) every cycle for 4 cycles. Bevacizumab and nitroglycerin transdermal patch until progression.
In the Netherlands the following NTG patches delivering 15 mg NTG per 24 h are available:
- Deponit 15
- Minitran 15
- Transderm-Nitro 15

All three patches are acceptable for this study.

Start date:
July 2010

Total:
222 patients

Study Coördinator:
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Centraal Data Management:
NVALT Datacenter, Amsterdam