NVALT 9 studie:

Titel:
Open label study to establish the efficacy of intravenous loading doses of Ibandronate 6 mg in patients with lung cancer and skeletal metastases experiencing moderate to severe bone pain: NVALT 9.

Primary objective:
The primary objective is to establish the efficacy of ibandronic acid in patients with lung cancer and painful metastatic bone disease and pain responses over a 7 day period.

Secundary objectives:

- Mean WORST PAIN scale of the BPI over time (first 7 days)
- Interference scales of the BPI (individually and total score)
- Analgesic consumption, expressed as Opioid equivalents
- WHO performance score
- QoL assessment
- Safety

Treatment:
Ibandronic acid (6 mg in 500 ml infusions over 15 minutes) days 1, 2, and 3

Start date:
Augustus 2007

Total :
53 patients

Study Coördinator:
Anne-Marie Dingemans, Academisch Ziekenhuis Maastricht

Centraal Data Management:
NVALT Data Center, Amsterdam