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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19953

Source
NTR

Brief title
NVALT-9 study

Health condition

Non small cell lung cancer (NSCLC)

Sponsors and support

Primary sponsor: NVALT-oncology
Source(s) of monetary or material Support: Roche Nederland BV

Intervention

Outcome measures

Primary outcome

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.

The main efficacy endpoint is bone pain response. In this study, pain response is defined as a:

25% decrease in mean pain score over a 3-day period (day 5,6 and 7) compared to pain score at baseline as determined by the “WORST PAIN” scale of the Brief Pain Inventory (BPI), with no more than a 25% increase in mean analgesic consumption over the same 3-day period compared to mean Baseline analgesic consumption.

Secondary outcome

1. Mean WORST PAIN scale of the BPI over time (first 7 days);

2. Interference scales of the BPI (individually and total score);

3. Analgesic consumption, expressed as Opioid equivalents;

4. WHO performance score;

5. QoL assessment;

6. Safety.

Study description

Background summary

Pain is a frequent symptom experienced by cancer patients. Increasing severity of pain is related to worse quality of life. While standard dosing of bisphosphonates results only in moderate bone pain relief, some open label studies showed dramatic and rapidly relief of moderate to severe bone pain with intravenous loading doses of ibandronate. In patients with hormone refractory prostate cancer and bone ibandronate was evaluated in an open-label non-randomized study. Patients (n=45) received 6 mg ibandronate i.v. for sequential days, followed by 6 mg ibandronate i.v. every 4 weeks. Significant pain reduction was observed in 895 of patients and 25% of patients were pain free after treatment (Ohlmann, Support. Care

Cancer, 2003, 11:396). A pilot study in 18 patients with metastatic bone disease the effect of short term intensive treatment with iv ibandronate on opioid-resistant bone pain was studied. A significant reduction in bone pain scores was observed within 7 days and sustained during the study period of 6 weeks (14).

Study objective

In lungcancer bone metastases appear frequently en they are an important cause of pain. The expectation is that Bondronat® gives a fast pain reduction.

In this phase II study will be examined whether this fast pain reduction indeed occurs and if the endpoint will be reached, a phase III study will follow.

Study design

This is an open label, multicenter phase II study. All patients will receive 6 mg ibandronate i.v. in a 15 minute infusion on day 1, 2 and 3 and a follow-up of 7 days. All patients will be followed for spontaneous adverse event reports for 28 days.

Intervention

Ibandronic acid 6 mg i.v. infusion over 15 minutes Days 1, 2, and 3.

Contacts

Public
NVALT Datacenter
NKI-AVL
Plesmanlaan 121
D.J. Storm
Amsterdam 1066 CX
The Netherlands
Scientific
NVALT Datacenter
NKI-AVL
Plesmanlaan 121
D.J. Storm
Amsterdam 1066 CX
The Netherlands

Eligibility criteria

Inclusion criteria

1. Patients with MBD due to histology or cytology confirmed NSCLC;

2. MBD confirmed by bone scintigraphy, MRI, CT-scan, PET scan or X-ray or cytohistological proven;

3. mean bone pain score „d 5 over the last 7 days on the WORST PAIN scale on the BPI;

4. bone pain must correspond to areas of metastases on bone scintigraphy, MRI, CT-scan, PET scan or X-ray. It is the investigators responsibility to insure that the pain is mainly due to MBD;

5. the use of at least a NSAID or a weak opioid based on the WHO analgesic ladder step 2;

6. no indication for radiotherapy for myelum compression;

7. adequate renal function (creatinine clearance as calculated by Cockroft-Gault method > 50 ml/min);

8. life expectancy at least 1 month;

9. age > 18 years;

10. written informed consent;

11. able to comply with study measurements i.e. brief pain inventory and QoL assessments.

Exclusion criteria

1. Other active malignancies;

2. nursing mothers;

3. pregnancy;

4. patients with impending pathological fracture or spinal cord compression;

5. bone radiotherapy in the preceding 4 weeks;

6. bisphosphonate treatment in the previous 2 months;

7. hypercalcemia (serum calcium, albumin corrected „d 2.7 mmol/l);

8. hypocalcemia (serum calcium, albumin corrected < 2 mmol/l);

9. primary hyperparathyroidism;

10. known Paget¡¦s disease of the bone;

11. start of anti tumor treatment in 4 weeks before study entry;

12. patients with known hypersensitivity to any of the components of ibandronic acid;

13. delirium or confusion;

14. treatment with aminoglycoside antibiotics < 4 weeks before start study treatment;

15. start or increase of dose of corticosteroids in preceding week.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-12-2007
Enrollment:	53
Type:	Actual

Ethics review

Positive opinion

Date:	23-12-2008

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1531
NTR-old	NTR1602
Other	MEC : 07-2-035.6/ivb.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A