

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.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19953

Bron

Nationaal Trial Register

Verkorte titel

NVALT-9 study

Aandoening

Non small cell lung cancer (NSCLC)

Ondersteuning

Primaire sponsor: NVALT-oncology

Overige ondersteuning: Roche Nederland BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 rapid 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 89% 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).

Doel van het onderzoek

In lungcancer bone metastases appear frequently and 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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 Cockcroft-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	28-12-2007
Aantal proefpersonen:	53
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	23-12-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A