A randomized phase III study of i.v. zoledronate (administered for 12 versus 36 months) as an adjunct to standard therapies in the treatment of multiple myeloma. A phase III study.

Gepubliceerd: 06-09-2005 Laatst bijgewerkt: 18-08-2022

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

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

Samenvatting

ID

NL-OMON26780

Bron
NTR

Verkorte titel
HOVON 50 MM

Aandoening

Multiple Myeloma

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
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Overige ondersteuning: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to the occurence of the first skeletal related event, from randomization.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase:

Phase III.

Study objectives:

Evaluation of the effect of zoledronate i.v. treatment duration in addition to chemotherapy.

Patient population:

Patients with multiple myeloma, previously untreated, Salmon & Durie stage II or III, age >= 18 years, included in HOVON 49 or HOVON 50 trial.

Study design:

Prospective, multicenter, randomized.

Duration of treatment:

Expected duration of zoledronate treatment is 12 months in arm A and 36 months in arm B.

Number of patients:

244 randomized patients (which corresponds with about 407 registered patients).

Doel van het onderzoek

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

All patients will receive Zoledronate 4 mg as a 15-minute i.v. infusion every 4 weeks for 12 months.
After 12 months these patients will be randomized between:

- Arm A: Off treatment

- Arm B: Zoledronate 4 mg as a 15-minute i.v. infusion every 4 weeks for 24 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with a confirmed diagnosis of multiple myeloma stage II or III according to the Salmon & Durie criteria;

2. Patients with at least one osteolytic bone lesion on conventional radiographs (plain film);

3. Inclusion in HOVON 49 or HOVON 50 trial;

4. Inclusion in HOVON 57 at the same time as inclusion in HOVON 49 or HOVON 50;

5. Date of inclusion in HOVON 57 trial before date start chemotherapy HOVON 49 or HOVON 50;

6. Age >=18 years;

7. WHO performance status 0-3;

8. Negative pregnancy test at inclusion if applicable;

9. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Treatment with bisphosphonates at any time during the 12 months prior to registration. Exception: patients may have received up to 3 doses of a bisphosphonate for hypercalcaemia provided this has been administered > 14 days prior to registration;

2. Corrected (adjusted for serum albumin) serum calcium < 2.00 mmol/l or > 2.80 mmol/l;

3. Serum creatinin > 265 micromol/l;

4. Total bilirubin > 30 micromol/l;

5. Patients unwilling or unable to comply with protocol;

6. Severe cardiac dysfunction (NYHA classification III-IV);

7. Patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates;

8. Patients who are not willing or capable to use adequate contraception during the therapy (all men, all pre-menopausal women);

9. Lactating patients if applicable.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	19-04-2004
Aantal proefpersonen:	407
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2005
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	NL196
NTR-old	NTR233
Ander register	: HO57
ISRCTN	ISRCTN23172547

Resultaten

Samenvatting resultaten
N/A