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.

No registrations found.

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

Summary

ID

NL-OMON26780

Source
NTR

Brief title
HOVON 50 MM

Health condition

Multiple Myeloma

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
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Source(s) of monetary or material Support: Stichting Hemato-Oncologie voor

Volwassenen Nederland (HOVON)
Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. The incidence of SREs per patient in the first 36 months from randomization;

2. Time to first SRE from registration;

3. Time to progression of bone metastasis;

4. Time to overall progression of disease;

5. Performance status (WHO);

6. Quality of life (QLQ-C30);

7. Bone resorption markers;

8. Objective bone lesion response from radiological studies.

Study description

Background summary

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).

Study objective

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

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2004
Enrollment:	407
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
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	NL196
NTR-old	NTR233
Other	: HO57
ISRCTN	ISRCTN23172547

Study results

Summary results
N/A