

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

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 17/11/2008	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

HO57; NTR233

Study information

Scientific Title

Acronym

HOVON 50 MM

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple myeloma

Interventions

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 randomised between:

1. Arm A: off treatment
2. Arm B: zoledronate 4 mg as a 15-minute i.v. infusion every 4 weeks for 24 months

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Zoledronate

Primary outcome(s)

Time to the occurrence of the first skeletal related event, from randomisation.

Key secondary outcome(s)

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

Completion date

19/04/2007

Eligibility

Key inclusion criteria

1. Patients with a confirmed diagnosis of multiple myeloma stage II or III according to the Salmon and 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. Aged greater than or equal to 18 years
7. World Health Organization (WHO) performance status 0 - 3
8. Negative pregnancy test at inclusion if applicable
9. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Treatment with bisphosphonates at any time during the 12 months prior to registration. Exception: patients may have received up to three doses of a bisphosphonate for hypercalcaemia provided this has been administered greater than 14 days prior to registration
2. Corrected (adjusted for serum albumin) serum calcium less than 200 mmol/l or greater than 280 mmol/l
3. Serum creatinine greater than 265 micromol/l
4. Total bilirubin greater than 30 micromol/l
5. Patients unwilling or unable to comply with protocol
6. Severe cardiac dysfunction (New York Heart Association [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

Date of first enrolment

19/04/2004

Date of final enrolment

19/04/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus University Medical Centre

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (Netherlands)

ROR

<https://ror.org/056kpx27>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (The Netherlands)

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes