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

# Plain English summary of protocol

Not provided at time of registration

# Study website

http://www.hovon.nl

# Contact information

# Type(s)

Scientific

#### Contact name

Prof P Sonneveld

#### Contact details

Erasmus University Medical Centre Department of Haematology P.O. Box 2040 Rotterdam Netherlands 3000 CA +31 (0)10 463 3589 p.sonneveld@erasmusmc.nl

# Additional identifiers

EudraCT/CTIS number

#### IRAS number

## ClinicalTrials.gov number

# Secondary identifying numbers

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

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

# 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 measure

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

#### Secondary outcome measures

- 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

#### Overall study start date

19/04/2004

## 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** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

407

# 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)

# Sponsor details

Vrije University Medical Centre (VUMC) PO Box 7057 Amsterdam Netherlands 1007 MB +31 (0)20 444 2693 hdc@hovon.nl

#### Sponsor type

Research organisation

#### Website

http://www.hovon.nl/

#### **ROR**

https://ror.org/056kpdx27

# Funder(s)

# Funder type

Research organisation

#### **Funder Name**

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

#### Funder Name

The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (The Netherlands)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration