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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
17/11/2008

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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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)
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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