Assessment of the prognostic value of MM related bone disease as detected by Whole Body X Ray (WBXR), Whole Body - Magnetic Resonance Imaging (WB-MRI) and FluoroDeoxyGlucose - Positron Emission Tomography - Computer Tomography (FDG-PET-CT) at diagnosis (part I) and in follow-up (part II)

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Primary objective: To assess the prognostic value of MM related bone disease as detected by WBXR, WB-MRI and FDG-PET-CT in terms of progression free survival. To determine the conversion rate, defined as complete normalization, of FDG-PET-CT, after...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Plasma cell neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON36434

Source
ToetsingOnline

Brief title
Prognostic value of MM bone disease detected by 3 imaging techniques

Condition

- Plasma cell neoplasms

Synonym
Kahler's disease, Multiple Myeloma

Research involving
Human

Sponsors and support

Primary sponsor: HOVON
Source(s) of monetary or material Support: Ministerie van OC&W,HOVON

Intervention

Keyword: bone disease, magnetic resonance imaging (MRI), multiple myeloma, positron emission tomography (PET)

Outcome measures

Primary outcome

Progression free survival, defined as time from registration to progression or

death from any cause [part I only]

Conversion rate, defined as complete normalization, of FDG-PET-CT and MRI [part

II only]

Secondary outcome

Clinically symptomatic bone disease defined as fractures and lesions needing

radiotherapy and/or surgery

Clinically symptomatic bone disease defined by the EORTC QLQ-MY20 measuring

specific aspects of multiple myeloma, i.e. specific pain complaints.

Overall survival, measured from time of registration

The number and distribution of lesions detected by the different imaging

techniques (at different time points [part II only])

Remission status as determined by the IMWG criteria after three induction

cycles and after completion of induction therapy [part II only]

Study description

Background summary

Bone disease is common in patients with symptomatic/stage III Multiple Myeloma (MM), with up to 90% of patients developing bone lesions, which causes major morbidity.
Routinely, conventional 'whole body X-ray' (WBXR) analysis is used to evaluate and asses the presence of bone disease. The sensitivity, however, is low compared to newer imaging technieques: MRI and (FDG-PET-)CT. Although the negative prognostic impact of the presence of bone lesions as detected by WBXR is clear and has been validated, there is less information on the prognostic value of the newer imaging techniques. Thus, to date, replacement of WBXR by one of the newer imaging techniques is not possible.
Currently evaluation of treatment is performed according to the IMWG criteria, using m-protein and clonal plasma cell count only. Evaluation of bone disease is not possible, since signs of MM related bone disease detected with WBXR will not disappear. Therefore remission cannot be judged by using WBXR. Earlier results show the value of the newer imaging techniques in follow up. Although especially FDG-PET-CT seems suitable it is not completely clear which one of the newer imaging techniques will be the most important in treatment evaluation.

A relation between the extent of bone disease and biological markers of bone disease and gene expression profiling has been demonstrated. It is however not yet clear which one of the imaging techniques shows the best correlation.

Study objective

Primary objective:
To assess the prognostic value of MM related bone disease as detected by WBXR, WB-MRI and FDG-PET-CT in terms of progression free survival.

To determine the conversion rate, defined as complete normalization, of

FDG-PET-CT, after 3 cycles and completion of therapy [part II only]

Secondary objectives:
To asses the prognostic value of MM related bone disease as detected by WBXR, WB-MRI and FDG-PET-CT in terms of clinically symptomatic bone disease

To asses the prognostic value of MM related bone disease as detected by WBXR, WB-MRI and FDG-PET-CT in terms of overall survival

To compare the number and distribution of lesions detected by WBXR, WB-MRI and FDG-PET-CT.

To assess the relation between the extent of MM related bone disease detected by WBXR, WB-MRI and FDG-PET-CT and biological features of MM bone disease as determined by DKK1 levels, sRANKL and osteoprotegerin.

To investigate distinct patterns of gene expression involved in MM related bone disease

To determine the conversion rate, defined as complete normalization, of MRI, after 3 cycles and completion of therapy [part II only]

To compare the response rate as determined by imaging techniques with classical response monitoring according to IMWG [part II only]

To assess and compare the prognostic value of mid- and post-treatment remission status as determined with imaging techniques and classical response monitoring in terms of PFS and OS [part II only]

To compare *classical* MRI with contrast-enhanced MRI and diffusion-weighted MRI with respect to focal lesions and diffuse infiltration by multiple myeloma [part II only]

Study design

Side study of HOVON 87

Study burden and risks

There is a burden of time: every scan takes 30 to 60 minutes. Thus, concerning patients participating in part II performing all scans will take 3 to 6 hours.

Patients will be asked to fill in questionnaires. These forms will be send to with the HOVON 87 questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion in the HOVON 87 study, concerning previously untreated patients with symptomatic multiple myeloma, age >65 or younger and ineligible for high dose therapy and peripheral stem cell transplantation.
To be included in part II, patients have to participate in part I of the study

Exclusion criteria

Contraindications for MRI (including e.g. pacemaker, ICD, metallic splinter in eye, hemostatic clips in CNS, claustrofobia, or other implants that are contraindicated according to the MRI operator*s discretion)
Physical inability to access either MRI or PET-CT facilities

Active, uncontrolled infections
Known or suspected hypersensitivity or intolerance to used contrast agents
Uncontrolled diabetes
Contraindications for (horizontal) immobilization during at least one hour [part II only]

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	15-04-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL30387.029.10