Prognostic value of bone disease in MM, an evaluation of different imaging techniques at diagnosis and in follow-up.

Gepubliceerd: 14-05-2010 Laatst bijgewerkt: 18-08-2022

Primary objective: 1. To assess the prognostic value of MM related bone disease as detected by FDG-PET in terms of progression free survival; 2. To determine the conversion rate, defined as complete normalization, of FDG-PET-CT, after 3 cycles...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27317

Bron
NTR

Aandoening

multiple myeloma
elderly (>65 years)
FDG-PET
MRI
CT
X-ray
diagnosis
follow-up

Ondersteuning

Primaire sponsor: HOVON
Overige ondersteuning: HOVON

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Progression free survival, defined as time from registration to progression or death from any cause [part I only];
2. Conversion rate, defined as complete normalization, of FDG-PET [part II only].

Toelichting onderzoek

Achtergrond van het onderzoek

Bone disease, defined as osteolytic lesions and osteoporosis, is common in patients with symptomatic/stage III Multiple Myeloma (MM), with up to 90% of patients developing bone lesions and up to 60% of patients experiencing a pathologic fracture in the course of the disease.

The sensitivity of conventional WBXR analysis is low, given that at least 30% of trabecular bone substance must be lost in order to give rise to visible lytic lesions. Recently, other imaging modalities including WB-MRI and FDG-PET-CT have become available, which in general are more sensitive than WBXR. Although the negative prognostic impact of the presence of bone lesions as detected by WBXR is clear and has been validated in differently treated patient populations, there is less information on the prognostic value of baseline MRI and even more sparse data concerning the other imaging techniques. Therefore it is necessary to investigate the prognostic impact of these newer imaging techniques before replacing WBXR.

Currently, bone Currently remission status is being performed according to the IMWG criteria, measuring m-protein levels and clonal plasmacell counts. Bone disease as indicated by WBXR is only being monitored to exclude progression, as generally no responses can be observed. Based on earlier research it is suggested that normalization of bone disease detected by newer imaging was prognostic importance. It is not clear which imaging technique is most suitable for respons evaluation.

Therefore every patient will undergo WB-MRI and FDG-PET-CT before start of treatment and after the third and ninth chemotherapy cours this will be repeated in half of the included patients.

Doel van het onderzoek

Primary objective:

1. To assess the prognostic value of MM related bone disease as detected by FDG-PET in terms of progression free survival;

2. 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:

1. To assess the prognostic value of MM related bone disease as detected by WBXR, WB-MRI and CT in terms of progression free survival;

2. To assess the prognostic value of MM related bone disease as detected by WBXR, WB-MRI, CT and FDG-PET in terms of clinically symptomatic bone disease;

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

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

5. 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;

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

7. To determine the conversion rate, defined as complete normalization, of WB-MRI and contrast-enhanced MRI and diffusion-weighted MRI, after 3 cycles and completion of therapy [part II only];

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

9. 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];

10. 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].

Onderzoeksopzet

1. Diagnosis;

2. 3 months (after 3th cycle of chemotherapy);

3. 9 months (after 9th cycle of chemotherapy).

Onderzoeksproduct en/of interventie

1. FDG-PET-CT before treatment (60 patients) in follow up after 3th and 9th chemotherapy cycle (30 patients);

2. MRI before treatment (60 patients) in follow up after 3th and 9th chemotherapy cycle (30 patients);

3. Questionnaires before treatment (60 patients) in follow up after 3th and 9th chemotherapy cycle (30 patients);

4. OPG, sRANKL and DKK-1 before treatment in follow up after 3th and 9th chemotherapy cycle .

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Inclusion in the HOVON 87 study;

2. To be included in part II, patients have to participate in part I of the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. 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);

2. Physical inability to access either MRI or PET-CT facilities;

3. Active, uncontrolled infections;

4. Known or suspected hypersensitivity or intolerance to used contrast agent;

5. Impaired renal function: clearance ≤ 40 ml-min;

6. Uncontrolled diabetes;

7. Contraindications for (horizontal) immobilization during at least one hour [part II only].

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2010

Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2208
NTR-old	NTR2332
Ander register	METc VUmc : 2010/7
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A