The predictive value of 18F-FDG-PET to demonstrate disease activity in patients with relapsed multiple myeloma; a pilot study

Published: 18-02-2009
Last updated: 05-05-2024

To demonstrate the accuracy of FDG-PET for defining disease activity in relapsed MM patients in comparison to X-ray and somatostatin receptor scintigraph (SRS).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational invasive

Summary

ID

NL-OMON32803

Source
ToetsingOnline

Brief title
FDG-PET in relapsed MM.

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
Kahler's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FDG-PET, relapsed multiple myeloma (MM)

Outcome measures

Primary outcome

- To define the increase of FDG-PET uptake in relapsed MM in comparison to SRS

and X-ray examination.

Secondary outcome

Not applicable

Study description

Background summary

Multiple Myeloma (MM) is clonal B cell disorder characterised by a monoclonal plasma cell population in bone marrow, with bone pain, hypercalceamia, and kidney dysfunction as clinically presenting symptoms. Post-treatment the X-ray abnormalities persist and no distinction can be made at an early time point whether vital tumour cells are still present or whether the skeleton abnormalities contain normal cells. FDG-PET has been used to study the metabolic activity of the malignant plasma cells. Several small studies have demonstrated that osteolytic lesions might be FDG-PET positive due to their higher metabolic activity. The degree of uptake can be quantified which might indirectly be an indicator of the malignant character of the plasma cells.

Study objective

To demonstrate the accuracy of FDG-PET for defining disease activity in relapsed MM patients in comparison to X-ray and somatostatin receptor scintigraph (SRS).

Study design

Pilot study; Patients with relapsed MM are first seen by their haematologist at the out-patient clinic for follow-up. In case patients fulfill the inclusion criteria , they will be referred to the department of Nuclear Medicine and Molecular Imaging (NMMI) for FDG-PET scanning in conjunction other disease

related parameters.

Study burden and risks

- The radiation dose is 7.6 mSv for a patient weighing 80 kg for the FDG PET.
- To perform a FDG-PET scan.

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

Relapsed multiple myeloma patients that demonstrate increased disease activity

Exclusion criteria

-Ineligible to perform a scan
-Age <18 years.
-Pregnancy.
-Severe kidney dysfunction; serum-creatinine >=250 µM.

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):	01-01-2009
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL25318.042.08