Somatostatin receptor scintigraphy in patients with multiple myeloma or plasmocytoma

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Objective of the studyThe present pilot study will be focused to define the sensitivity of SRS in MM patients and in patients with plasmacytoma. This in comparison to X-ray examination. In addition it will be investigated whether SRS can be used as...

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

Summary

ID

NL-OMON30229

Source
ToetsingOnline

Brief title
Octreotide scan in multiple myeloma.

Condition

- Plasma cell neoplasms
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
Multiple myeloma, plasmacytoma

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: Multiple myeloma, radionuclide imaging

Outcome measures

Primary outcome

Study parameters

In this pilot study a limited number of patients will be analysed to define whether SRS is a feasible approach for diagnostic or prognostic purposes in MM or plasmacytoma. Thirty newly diagnosed upfront patients and 15 relapsed patients will be investigated. In these patients the following items will be investigated:

-To define the sensitivity of SRS in MM and plasmacytoma in comparison to X-ray examination.
-To test whether SRS can be used as alternative approach to detect skeleton abnormalities for painful affected areas in the case no abnormalities are observed on X *ray examination.
-Correlates the SRS uptake with clinical parameters that defines an aggressive MM and disappear the increased uptake upon treatment with intensive chemotherapy and ASCT and or radiotherapy. Subsequently patients treated according to the Hovon-65 protocol will be re-evaluated after 4 courses of chemotherapy but before the ASCT. Patients with a plasmacytoma will be re-evaluated 2 months after the radiotherapy course.

Secondary outcome

Not applicable.

Study description

Background summary

Multiple Myeloma

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. In the majority of the patients the disorder is disseminated through the bone marrow compartment but in 5% of the patients MM presents as localized disorder i.e. a plasmacytoma. The abnormalities of the skeleton can be identified by X-ray examination and demonstrates frequently the characteristics osteolytic defects9. However, in 30%-40% of the patients no osteolytic defects can be demonstrated but only osteoporosis. Post-treatment the X-ray abnormalities persist and no distinction can be made at an early time point whether vital tumor cells are still present or whether the skeleton abnormalities contain normal cells. Sofar only FDG-PET has been used to study the metabolic activity of the malignant plasma cells9-11. Several small studies have demonstrated that osteolytic lesions might be FDG-PET positive due to their higher metabolic activity.
Different in vitro studies have demonstrated that the somatostatin receptor is expressed on malignant plasma cells12-13. However, so far no clinical studies have been published in MM with SRS. Especially in view of the high somatostatin receptor expression it is conceivable that SRS might be a good alternative to the study the presence of the malignant plasma cells. The whole body scan might be of value to demonstrate whether a localized versus disseminated disorder is present. Clinically this is an important question since patients with localized disease are treated with high dose radiotherapy while patients with a disseminated disorder are treated with intensive chemotherapy including autologous stem cell transplantation14. An additionally value of this scanning technique is that the degree of uptake can be quantified which might indirectly be an indicator of the malignant character of the plasma cells as has been demonstrated for FDG-PET in lymphoma patients. Patients with a high FDG-PET uptake did have an aggressive lymphoma15.
Preliminary results in 4 MM or plasmacytoma patients demonstrated a high SRS binding in some of the affected areas (histological proven) which normalized after chemotherapy in two MM patients.
Based on these results it is of clinical relevance to study the value of SRS in MM patients and to what extent it can be used as marker for localized or

disseminated disorder.

Study objective

Objective of the study

The present pilot study will be focused to define the sensitivity of SRS in MM patients and in patients with plasmacytoma. This in comparison to X-ray examination. In addition it will be investigated whether SRS can be used as an alternative approach to detect skeleton abnormalities for painful affected areas in the case no abnormalities on X-ray examination can be observed including in patients with relapse MM. Bone pain is the most frequent symptom in MM. Finally the SRS uptake will be quantified to demonstrate whether the degree of uptake correlates with known prognostic scores and might disappear in the case of responsive disease upon intensive chemotherapy and ASCT.

Study design

Study design

In patients with newly diagnosed MM or plasmacytoma SRS will be performed in conjunction with the additional work-up that will be performed according to the ongoing HOVON 49 and HOVON 65 studies or according to accepted international guidelines9. In MM patients with painful affected area*s SRS will be performed in conjunction with X-ray examination which might be extended with CT-scan or MRI on basis of clinical indication.

Study burden and risks

- No specific risk
- The burden to visit the hospital and to undergo the 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

-Upfront patients with MM that are treated according to the HOVON-49 or HOVON-65 protocol.
-Upfront patients with plasmacytoma.
-Relapsed MM patients with painful affected areas.

Exclusion criteria

-Radiotherapy lasting longer than 5 days ago in the last 3 months.
-Ineligible to perform a scan.
-Age under 18 years.
-Pregnancy
-Severe kidney-dysfunction

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	45
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	octreoscan

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
EudraCT	EUCTR2006-004737-14-NL
CCMO	NL14066.042.06