Study on intracranial meningioma using PET ligand investigation during follow-up over years [SIMPLIFY]

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Compare the combined MRI/MET-PET report to the MRI-only report.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON44234

Source
ToetsingOnline

Brief title
MET PET meningeoma

Condition

- Nervous system neoplasms benign

Synonym
brain tumor; tumor of brain coverings

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: Meningioma Methionine PET

Outcome measures

Primary outcome

Difference (progression or not) between the MRI-only report and the MRI/MET-PET

report

Secondary outcome

Not applicable

Study description

Background summary

Meningiomas are a common type of intracranial tumor. Although meningiomas often are histopathologically benign, their localization can lead to severe neurologic disturbances, such as epilepsy and cranial nerve deficits. Particularly meningiomas of the skull base and/or near large vascular structures are notorious. Treatment consists of surgery, radiotherapy or a combination of both. Treatment planning and follow-up can be troublesome when based on conventional contrast-enhanced MRI: 1. The distinction between post-operative and post-radiotherapy tissue enhancement ('scar tissue'or 'radionecrosis') and tumor remnant is difficult. 2. The identification of tumor invasion in venous structures, e.g. cavernous sinus and superior sagittal sinus is difficult. 3. The judgment of possible invasion in bony structures of the skull base can be difficult. 4. It is problematic to evaluate tumor invasion in a contrast-enhancing 'dural tail' on MRI.
The PET-tracer 11C-methionine is involved in the amino-acid metabolism and is used for diagnostic PET-scanning (MET-PET) purposes in different types of intracranial diseases. With this type of investigation information about the metabolism of a lesion is obtained.
Based on the literature MRI and PET have proven to be complementary diagnostic tools in many oncologic conditions. The first renders mainly structural (anatomic) information and the latter mainly molecular (metabolic) information. With this study we want to investigate if combined MRI/MET-PET investigation leads to a different conclusion/interpretation than MRI-scanning only.

Study objective

Compare the combined MRI/MET-PET report to the MRI-only report.

Study design

35 patients with intracranial meningioma, who received stereotactic radiotherapy (with a pre-radiotherapy MET-PET for radiation planning purposes) and a longterm follow-up (of preferably > 5 years), will be asked to undergo MET-PET again in adjunct to their regular follow-up MRI-scan.
For each participant a separate MRI/MET-PET and MRI-only report will be made. Agreement between these reports will be calculated (Cohen's kappa).

Study burden and risks

Patients will have to make one extra hospital visit. We will try to combine MRI and MET-PET scanning on the same day, but often this will not be possible due to logistics.
The MET-PET scan will take approximately 40 minutes. Patients will haven an IV access line placed in their arm or hand. The total hospital visit will take approximately 60 minutes.
MET-PET scanning is regularly performed for many different clinical indications. Until now no adverse events have been encountered with this type of investigation in our hospital. No adverse events of this type of scanning have been described in the literature.

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

- Age above 18 years
- Profound understanding of the Dutch language
- Treatment with SRT for a intracranial meningioma with a pre-treatment MET-PET for radiation field planning purposes.
- Able to give written informed consent

Exclusion criteria

- Adverse reaction during previous MET-PET scan
- Pregnancy

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):	05-10-2018
Enrollment:	35

Type:	Actual

Ethics review

Approved WMO Date:	13-02-2018
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

ID: 25844
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63750.042.17
OMON	NL-OMON25844