Pilot feasibility of 11C-MET-PET as a post-surgery baseline scan in the follow-up of high-grade gliomas for the detection of tumor recurrence

Published: 25-01-2016
Last updated: 21-04-2024

A pilot study of the feasibility of 11C-MET as postoperative baseline scan in the follow-up of high-grade gliomas for the detection of tumor recurrence.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42285

Source
ToetsingOnline

Brief title
Pilot viability of 11C-MET-PET as a post-surgery baseline scan.

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
braintumour, GBM

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: 11C-methionine PET, Glioma, Pilot, Post-operative

Outcome measures

Primary outcome

The 11C-MET-PET within 48 hours postoperatively will be assessed visually and quantitatively and compared with the preoperative 11C-MET-PET scan. The 11C-MET-PET data will also be checked by comparison with the results of the advanced MRI sequences.

Secondary outcome

Not applicable.

Study description

Background summary

The tracer 11C-methionine (11 C-MET) is used as a specific cell proliferation tracer which shows metabolically active tumordeposities. A healthy brain barely takes up 11C-MET, causing the difference between the background and the tumor to be realively high. In addition, there is relatively little 11C-MET uptake in inflammatory processes. This makes 11C-MET a very suitable positron emission tomography (PET) tracer in order to differentiate between tumor progression and therapy changes. The latter is a major clinical problem for which further investigation is necessary.
In order to be able to make this differentiation, a direct post-operative baseline scan is required. With regard to the advanced MRI sequences, it is known that it is necessary to produce the post-operative baseline scan within 48 hours. After that timeframe, operation induced changes start to occur, such as granulation tissue. In that case the interpretation of the scan is no longer possible. Immediately postoperatively (<48 hours) 11C-MET has never been used before. Therefore, it is unknown whether 11C-MET provides a good baseline scan directly after surgery. This pilot will investigate the feasibility of this 11C-MET baseline scan and comparison the results with the advanced MRI sequences.

Study objective

A pilot study of the feasibility of 11C-MET as postoperative baseline scan in the follow-up of high-grade gliomas for the detection of tumor recurrence.

Study design

Conventional MRI, advanced MRI and 11C-MET-PET will be conducted on the same day. The advanced MRI will consist of diffusion weighted imaging (DWI), perfusion imaging by contrast technique (DSC) and spectroscopy (MRS). The post-operative MRI and PET scan will be produced within 48 hours after surgery (with the aim that operative effects are not visible on the baseline scan). This corresponds to the current practice of conventional MRI follow-up at the end of the radiotherapy.
The comparison with the pre-operative scan is to assess the viability of the post-operative scan. It will assessed whether the preoperative tumor uptake will disappear in accordance to the resection, as shown by the advanced MRI sequences. In addition, it will be assessed whether there are no interfering postoperative effects. The 11C-MET-PET scans will be interpreted in comparison with the quantitative results obtained with advanced MRI sequences (perfusion / diffusion / oxygenation / spectroscopy). If an immediate postoperative 11C-MET-PET proves to be feasible, than this will provide a basis for further research. This future research consist out of the differentiation between tumor progression and therapy change, one of the most urgent clinical dilemmas in neuro-oncology.

Study burden and risks

Use of MRI and PET are very safe. The duration of the routine MRI scan will be 5 minutes longer, so 40 minutes instead of 35 minutes. A PET scan will also be manufactured on the same day extra after intravenous injection of 11C-MET. In total, this takes 40 minutes (20 minutes contact time and 20 minutes scan time).

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

Patients with suspicion of newly diagnosed high-grade glioma who qualify for the standard treatment. Written informed consent

Exclusion criteria

Patients with recurrent high-grade glioma or other brain tumor as a secondary diagnosis are excluded. In addition, all patients who have had previous brain surgery or radiotherapy to the brain are also excluded. Patients with only a biopsy will be excluded. Patients under the age of 18 years will not be included. General exclusion criteria for MRI are exclusion criteria for participation in this study. The general MRI exclusion criteria are: not MRI compatible ferromagnetic material, pregnancy (or presumption thereof) and claustrophobia.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	25-01-2016
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
ClinicalTrials.gov	NCT02585219
CCMO	NL50485.042.14