18F-PSMA PET/CT for visualization of glioblastoma multiforme

Published: 07-11-2018
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Primary objective: * Determine the feasibility of using 18F-PSMA PET/CT for visualization of GBM.Secondary objectives:* Correlate PSMA RNA and protein expression with 18F-PSMA PET/CT uptake.

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

Summary

ID

NL-OMON48577

Source
ToetsingOnline

Brief title
PSMA-GBM

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
glioblastoma multiforme, high grade glioma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: glioblastoma multiforme, PSMA-PET

Outcome measures

Primary outcome

* The uptake of 18F-PSMA PET/CT in suspected GBM lesions

These data will be presented in a quantitative way. Activity is determined in a volume of interest (VOI) based on a relative threshold (>70% of the maximum voxel value within the VOI : VOI70%). Maximum standardized uptake in this VOI (SUVmax) and target to background ratios (TBR) are determined.

Secondary outcome

* The correlation between PSMA protein and RNA expression with 18F-PSMA PET/CT uptake.

PSMA protein and RNA expression will be presented in a quantitative way (FPKM as determined in targeted RNAsequencing analysis), and it will be plotted against 18F-PSMA uptake (SUVmax). Correlation will be described with the Pearsons correlation coefficient.

* Correlation between 18F-PSMA PET/CT and T1GdMRI

Qualified radiologist and nuclear medicine physician will review the images and compare them qualitatively (tumor delineation etc).

Study description

Background summary

Currently, diagnosis of brain tumours is based on conventional gadolinium enhanced T1-weighted magnetic resonance imaging (T1w-Gd MRI), which provides images with high spatial resolution. It may however be difficult to differentiate brain tumours from signal abnormalities caused by non-neoplastic alterations in the tissue, especially after surgery, radiotherapy and chemotherapy. Therefore, imaging biological and molecular characteristics by positron emission tomography (PET) has gained attention.
2-[18F]-fluoro-2-deoxy-D-glucose (FDG) is widely used in oncology, but due to high rate of glucose metabolism in normal brain, it is difficult and often impossible to distinguish tumour tissue using this tracer. Glioblastoma multiforme (GBM) is a highly vascularised tumour. Previous studies have shown that prostate-specific membrane antigen (PSMA) is robustly expressed by the tumour vascular endothelium of GBM and thus could be an interesting target for diagnosis and treatment.

Study objective

Primary objective:
* Determine the feasibility of using 18F-PSMA PET/CT for visualization of GBM.
Secondary objectives:
* Correlate PSMA RNA and protein expression with 18F-PSMA PET/CT uptake.

Study design

5 patients with detected/suspected GBM on T1w-Gd MRI will be included. On the day before surgery, patients will undergo a MRI scan with gadolinium contrast agent as standard pre-operative imaging for neuronavigation. Subsequently, patients will be injected with 200 MBq 18F-PSMA, and undergo a PET/CT scan 120 minutes post-injection, as under these conditions high tracer uptake and high tumor-to-background ratios have been observed in patients with prostate cancer. After this scan patients will be hospitalized at the department of neuro-surgery. The next day, tumour tissue will be resected and processed following standard procedures for histological/immunohistochemical analysis by the pathology department. From the resected material, additional pieces of tissue will be frozen for PSMA protein and targeted RNA expression analysis to determine correlations with tracer uptake.

Study burden and risks

The risk of serious side effects of the study medication is absent to minimal. Bruising may occur after the venous puncture, measures like application of local pressure will be taken to minimize the risk. Furthermore the expected radiation dose is low (4,7 mSv), especially in comparison to the post-operative radiotherapy these patients will receive.
Because of its high soft-tissue contract, MRI is still the first method of choice for the assessment of brain tumors, however it has certain limitations.

These limitations include defining of tumor extension and grade, and differentiation of tumor recurrence from necrosis or scarring. The use of FDG-PET to distinguish recurrent tumor from radiation necrosis appeared promising, however the high uptake in normal brain tissue imposes some difficulties. 18F-FET has already been proven to outperform MRI and FDG-PET in tumor delineation and identification of tumor recurrence in various clinical trials, and because of its specificity for tumor vasculature, we expect the same for 18F-PSMA-PET. This is why implementation of this technique in the Radboudumc would be of benefit for glioma patients.

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

- Suspected GBM on MRI scan, - Scheduled for tumor resection at Radboudumc, -

Age *18 years

Exclusion criteria

- Age < 18 years, - Pregnancy or the wish to become pregnant within 6 months, - Creatinine clearance below 40ml/min, - Liver disease defined as aspartate aminotransferase or alanine aminotransferase level of more than three times the upper limit of normal range

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-02-2019
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	18F-PSMA
Generic name:	18F-PSMA

Ethics review

Approved WMO

Date:	07-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2018-000046-19-NL
CCMO	NL64616.091.18