FET-PET-Guided management of pseudoprogression in Glioblastoma

Published: 31-05-2024
Last updated: 07-06-2024

We aim to determine the added value of a direct FET-PET for clinical practice. The hypothesis is that the addition of FET-PET will lead to correct diagnosis more rapidly than regular MRI alone, and thus to a better quality of life for patients...

Ethical review	Approved WMO
Status	Pending
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON56794

Source
ToetsingOnline

Brief title
The FET POPPING trial

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, Glioblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW,CURIUM PET FRANCE

Intervention

Keyword: FET-PET, Glioblastoma, Nuclear medicine, Pseudoprogression, Radiotherapy

Outcome measures

Primary outcome

1. The percentage of patients undergoing unnecessary interventions: diagnostic biopsies, surgeries, medications.

2. Health related quality of life (EQ5D, EORTC-QLQ-BN20, iPCQ and iMCQ) at 12 weeks

Secondary outcome

-Time-to-diagnosis (defined as index MRI to final treatment)

-Overall survival (defined from index MRI)

-Number of unnecessary treatment cycles

-Cost-effectiveness in QALYs and ICERs

-HRQOL (continuous measure): EQ5D, EORTC-QLQ-BN20, iPCQ and iMCQ at 6 weeks and 6 months

Study description

Background summary

Glioblastoma patients undergo postoperative chemoradiation. During follow-up, there is often an increase in MRI abnormalities, and distinguishing between

tumor growth and damage as a result of the treatment ('pseudoprogression') is difficult. Techniques such as perfusion MRI can provide additional information, but uncertainty often remains, which can lead to incorrect or delayed diagnosis, leading to uncertainty, unnecessary treatment - even unnecessary surgery - or delay of adequate treatment. A new type of scan, the [18F] FET-PET, has a good discriminating power between pseudoprogression and tumor growth, but is still used infrequently due to costs, extra logistics, and doubt about clinical benefit.

Study objective

We aim to determine the added value of a direct FET-PET for clinical practice. The hypothesis is that the addition of FET-PET will lead to correct diagnosis more rapidly than regular MRI alone, and thus to a better quality of life for patients through earlier certainty, faster initiation of the adequate policy, fewer unnecessary examinations and treatments; and to a net decrease in healthcare costs.

Study design

Multicenter diagnostic randomized clinical trial.

Intervention

The use of FET-PET (in addition to MRI) to differentiate between tumor growth and
pseudoprogression.

Study burden and risks

FET PET is already implemented in daily clinical practice in some centers, with an associated negligible risk. Moreover, undergoing an additional PET scan and the completion of questionnaires is perceived as a relatively low and acceptable burden. This assessment considers the potential positive impact of FET PET on the individual participant.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with a glioblastoma, IDH-wildtype, WHO grade 4, according to WHO 2021 criteria. - Age >=18 years
- New or increased enhancement within the high-dose radiation field (defined as within the 80% isodose line) on follow-up MRI
- Follow up MRI >=3 months after the end of the standard-of-care temozolomide-based concomitant chemoradiation (short- and long course). Of note, very early increase - within 3 months of last radiation - will not be grounds for inclusion because of the high rate of pseudoprogression and slightly lower diagnostic performance of FET-PET compared to the situation of increase beyond 3 months after last radiation. Patients with such very early increase may have subsequent further increase after 3 months post-radiation, causing (further) diagnostic doubt; these may be included at that later timepoint if they meet the other inclusion criteria.
- First moment of clinicoradiological uncertainty regarding the diagnosis (>=3 months after the end of chemoradiation): pseudoprogression or tumor recurrence. The determination of *uncertainty* is made by the treating physician, preferably in the multidisciplinary tumor board, based on available

clinical and standard-of-care MRI-data, which generally includes perfusion-MRI. - Previous usage of bevacizumab as a symptom treatment is allowed. However, inclusion is only allowed at the first moment of clinical doubt between pseudoprogression and tumor recurrence, not at later timepoints.

Exclusion criteria

- Previous treatment for recurrence of disease
- An enhanced lesion size of less than 1 cm on the index MRI. In the newest RANO PET-criteria, it is advised to use FET-PET for increasing lesions only in cases with a minimum lesion size.
- Life expectancy of less than 6 months, determined by the treating physician
- Contra-indications for PET (claustrophobia, inability to lay still)
- Women of childbearing potential without adequate contraception
- Any other concomitant disease that may influence PET imaging or clinical outcomes of this study, this includes but is not limited to: cerebral inflammatory diseases and other cancers with brain- or leptomeningeal metastases.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2024
Enrollment:	144
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	31-05-2024
Application type:	First submission
Review commission:	METC NedMec

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	NL86008.041.24