Prospective Longitudinal Study Using Functional MRI and Met-PET Imaging for Treatment Evaluation in Glioblastoma Patients

Published: 06-03-2018
Last updated: 11-07-2024

This study aims to establish the diagnostic accuracy of functional MRI techniques and MET-PET individually and combined in treatment evaluation of glioblastoma.

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

Summary

ID

NL-OMON46687

Source
ToetsingOnline

Brief title
MRI and MET-PET treatment evaluation in glioblastoma

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Glioblastoma; Brain tumor

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: Glioblastoma, MRI, PET, Treatment evaluation

Outcome measures

Primary outcome

The diagnostic accuracy for differentiating between tumour recurrence and treatment effects will be compared for each imaging sequence independently and for the combinations. Longitudinal quantitative data will be extracted for each imaging technique.

Secondary outcome

not applicable

Study description

Background summary

Glioblastomas (GBM) are the most malignant brain tumours with low survival rates. Treatment failure causes this tumour to inevitably recur, making close monitoring of GBM patients essential. The gold standard for follow-up is anatomical MR imaging based on contrast enhancement. However, this imaging method is hindered by pseudo-progression which can resemble true tumour progression, but is in fact due to treatment effects.

Functional imaging methods have been employed to overcome the limitations of anatomical MRI by measuring biological aspects of the tumour. Cellular density, tumour neovascularisation and tumour metabolites can be visualised by diffusion MRI, perfusion MRI and MR spectroscopy, respectively. Increased metabolism associated with tumour tissue is detectable with methionine PET (MET-PET). Although these functional imaging techniques individually showed promising results in differentiating pseudo-progression from true tumour progression, a large prospective study comparing all techniques directly in the same patients is lacking.

Study objective

This study aims to establish the diagnostic accuracy of functional MRI techniques and MET-PET individually and combined in treatment evaluation of glioblastoma.

Study design

In this prospective longitudinal cohort study 40 primary glioblastoma patients will undergo multimodal MRI and MET-PET within 72 hours after surgery to acquire a baseline scan. Follow-up scans will be acquired 10 weeks after concomitant chemoradiotherapy (CCRT) and then with 3 months intervals until anatomical follow-up MRI is suggestive of tumour recurrence. The final diagnosis will be made radioclinically or histologically.

Study burden and risks

MRI and PET scanning is a routine and very safe procedure in clinical practice. Participation in this study will result in a prolongation of 10 minutes in MRI scanning. The extra PET scan has an additional scanning time of 25 minutes. As all glioblastoma patients will receive radiotherapy to the brain, irradiation from the PET is negligible.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1 Hanzeplein 1
Groningen 9700RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1 Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult patients with a new primary glioblastoma.
- Scheduled to undergo standard treatment consisting of surgical resection followed by concomitant chemoradiation and adjuvant chemotherapy according to the Stupp protocol.
- Informed consent must be obtained
- No exclusion criteria

Exclusion criteria

- Patients with a recurrent or secondary glioblastoma
- Patients with a other intracranial tumour
- Patients with infratentorial glioblastoma
- Prior brain surgery or irradiation of the head
- Patients not scheduled for standard therapy (e.g. who will receive a biopsy without further resection)
- Minors (<18 years of age)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-10-2017

Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2018
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: 23945
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63082.042.17