MRI and MET-PET treatment evaluation in glioblastoma

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23945

Source
Nationaal Trial Register

Brief title
MRI and MET-PET treatment evaluation in glioblastoma

Health condition

Glioblastoma; Glioblastoom

Brain tumour; Hersentumor

Magnetic Resonance Imaging

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

The primary outcome is to establish the diagnostic accuracy of functional MRI techniques and

MET-PET individually and combined in treatment evaluation of glioblastoma.

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.

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

Study objective

Our hypothesis is that a combination of functional MRI techniques and MET-PET shows a higher diagnostic accuracy than anatomical imaging or one functional MRI technique alone.

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.

Intervention

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

Contacts

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Eligibility criteria

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 other intracranial tumours

- 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 non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46687
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6536
NTR-old	NTR6724
CCMO	NL63082.042.17
OMON	NL-OMON46687

Study results