Accuracy of glioma imaging

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29302

Source
Nationaal Trial Register

Brief title
FRONTIER

Health condition

EN: glioma
NL: glioom

Sponsors and support

Primary sponsor: VU University medical center
Source(s) of monetary or material Support: Cancer Center Amsterdam (CCA2012-2-05)
Dutch Cancer Society (OAA/H1/VU 2015-7502)

Intervention

Outcome measures

Primary outcome

- Qualitative (high, normal or low signal) and quantitative parameters of MRI and PET for each biopsy site

- Qualitative (central glioma, glioma infiltration, normal brain or uninformative) histopathological score of each biopsy site

Secondary outcome

- Gene expression of each biopsy site

Study description

Study objective

1. Advanced neuroimaging, in combination with standard MRI, will have a superior diagnostic accuracy in comparison with standard MRI alone.

2. Histological and molecular characteristics of glioma will correlate better with advanced imaging than standard imaging.

Study design

Phase I (n=8) 12 months

Phase II (n=12) 12 months

Phase III (n=20) 12 months

Intervention

Observational study with PET and MRI previous to stereotactic biopsies in and around the tumor.

Contacts

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Eligibility criteria

Inclusion criteria

Patients of 18 years and older with a MRI interpretation by an expert neuroradiologist of a diffuse infiltrative glioma, and who have an indication, confirmed by the multidisciplinary neuro-oncology tumor-board, for resective surgery.

Exclusion criteria

Patients who are pregnant or underwent previous brain surgery, cranial irradiation or chemotherapy. Patients with other brain pathology on MRI, such as stroke or multiple sclerosis. Patients with a tumor located infratentorially or in the spinal cord.

Withdrawal criteria
Patients who do not successfully undergo one PET scan in phase I and III or both PET scans in phase II.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2015
Application type:	First submission

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
NTR-new	NL5205
NTR-old	NTR5354
Other	METC : 2013/335

Study results