Accurate delineation of glioma infiltration by advanced PET/MR neuro-imaging

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(1) to assess the diagnostic accuracy of advanced neuroimaging compared with standard MRI for the detection of diffuse glioma infiltration within the brain in newly diagnosed patients, (2) to histopathologically and molecularly characterize the...

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

Summary

ID

NL-OMON45242

Source
ToetsingOnline

Brief title
PET/MRI of glioma

Condition

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

Synonym
brain tumor

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biopsy, glioma, MRI, PET

Outcome measures

Primary outcome

Quantitative and qualitative imaging data from standard MRI (T1 without and with gadolinium, T2, 3D FLAIR), advanced MRI (DTI, perfusion-weighted MRI, MRS) and advanced PET (FET, CHO). Histopathological and molecular characterization of biopsy samples.

Secondary outcome

not applicable

Study description

Background summary

Extensive resection of diffuse infiltrative glioma (WHO grade 2-4) improves patient survival (Smith, J Clin Oncol 2008; Stummer, Neurosurg 2008). Standard MRI is used preoperatively to determine the target volume for resection as well as postoperatively to determine residual tumor before starting chemo-radiotherapy. Standard MRI, however, quite poorly detects glioma infiltration into surrounding normal brain tissue, leading to suboptimal resections and inadequate radiation therapy fields. Innovative imaging techniques such as advanced PET and MRI hold potential to provide more accurate delineation of glioma infiltration. A PET/MRI facility, which will be available in the Neuroimaging Center Amsterdam in 2012 as first in The Netherlands, can combine these techniques in one diagnostic session. The accuracy of these techniques for delineation of glioma infiltration has not been addressed.

Study objective

(1) to assess the diagnostic accuracy of advanced neuroimaging compared with standard MRI for the detection of diffuse glioma infiltration within the brain in newly diagnosed patients, (2) to histopathologically and molecularly characterize the central and infiltrative glioma areas and correlate the

results with imaging findings.

Study design

A monocenter prospective diagnostic observational study in 40 patients undergoing resective glioma surgery. Patients will have preoperative advanced neuroimaging in addition to standard MRI. Serial neuronavigated biopsies in and around the glioma boundaries obtained immediately preceding resective surgery will provide quantitative histopathological characteristics of the regions of interest, enabling comparison with quantitative measurements in the imaging modalities at the same biopsy sites. The study consist of two phases: eight patients in phase I as a pilot project to optimize imaging methodology and thirty-two patients in phase II to complete data acquisition for comparison of diagnostic accuracies.

Study burden and risks

We hypothesize that a combination of F18-fluoro-choline PET, MR spectroscopy using the choline to N-acetyl-aspartate index and standard MRI has superior accuracy compared to standard MRI alone. In addition, the biopsies of glioma infiltration will be compared to those from the core of the tumor to identify differentially expressed molecular targets as candidates for future PET tracer development.
Translation of this information into the clinic should improve delineation of glioma target volume, facilitating optimization of resective surgery and radiation therapy, resulting in better and prolonged survival. We will aim at a follow-up project with randomized comparison of advanced and standard neuroimaging-guided therapy with patient survival as primary outcome measure, with the potential to define a new standard of care.

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

* Adult (18 years and older)
* MRI interpretation of diffuse infiltrative glioma by an expert neuroradiologist
* Indication for resective surgery confirmed by the multidisciplinary neuro-oncology workgroup
* Written informed consent

Exclusion criteria

* Previous brain surgery, cranial radiotherapy or chemotherapy
* Other brain pathology on MRI, such as infarction or multiple sclerosis
* Tumor located infratentorially or in the spinal cord
* Estimated duration of surgery more than 440 minutes
* Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL45519.029.13