Vascular Signature Mapping of Brain Tumor Genotypes

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON55998

Source
ToetsingOnline

Brief title
VSM of Brain Tumors

Condition

- Miscellaneous and site unspecified neoplasms benign
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO-TTW,GE Healthcare,Philips

Intervention

Keyword: Glioma, Machine learning, MRI, Vascularization

Outcome measures

Primary outcome

The endpoint of the first part of the study is a novel MRI protocol for characterization of the vessel architecture, assessed with respect to the signal-to-noise ratio (SNR) and the ability to obtain vascular information. The main parameters that will be used for characterization of the vasculature are physiological parameters including the vessel architecture, cerebral blood volume (CBV), cerebral blood flow (CBF), mean transit time (MTT), and oxygenation level.

The main study end point of the second part of the study is the accuracy of automatic classification of the tumor*s genotype. The accuracy of the new method will be compared to the current state-of-the-art reference method based on conventional MRI.

Secondary outcome

Baseline characteristics of subjects (including age, sex, Karnofsky performance status, tumor histology, molecular parameters (1p/19q, Isocitrate Dehydrogenase (IDH1/2) and O6-Methylguanine-DNA Methyltransferase (MGMT) status), tumor location, supportive and antitumor treatment). In addition, the outcome (e.g. mortality, tumor progression, radiation necrosis, functioning of patients) will be used as study parameter. The outcome will be determined from the follow-up scans after 3 and 6 months, where the criterion for progression or

pseudo-progression is determined by the outcome of the scan.

Study description

Background summary

A glioma is a primary brain tumor in adults that is characterized by a highly variable, but overall poor survival. The optimal timing of treatment is in part determined by the expected biological behavior of the tumor. At present the expected biological behavior, determined by the tumor genotype, can only be determined by tissue analysis, which requires brain surgery. Non-invasive and improved diagnostic methods are sought to obtain insight into the molecular profile of the tumor and the expected biological behavior to avoid surgery performed solely for diagnostic purposes. Vascularization is an important aspect of the biological behavior of a primary brain tumor. Tumor vascularization characteristics can be assessed by Magnetic Resonance Imaging (MRI), but with the currently available technology this can only be achieved with unacceptably long scan times. In this proposal, we will develop and optimize a novel MRI protocol to gather a large set of quantitative vascularization parameters within an acceptable scan time. The hypothesis is that from such a *vascular signature* the tumor genotype can be inferred by means of machine learning.

Study objective

The primary objective is to develop and clinically validate a fast multi-parametric MRI acquisition technique, for non-invasive and comprehensive characterization of the tumor*s vascularization, *vascular signature mapping*, at 3 Tesla (3T) and 7 Tesla (7T) MRI. The secondary objective is to limit difficult and time-consuming visual interpretation of the acquired vascular information by developing a computer-aided diagnostic algorithm that automatically and accurately predicts the brain tumor genotype from the vascular signature maps.

Study design

The study *Vascular Signature Mapping for Brain Tumor Genotypes* is a multi-center observational diagnostic study, which consists of two parts. The first part of this study aims to develop and optimize a new MRI protocol that will exploit the effect of contrast agent on the MRI signal to infer information on the vascular properties of a tumor. It combines scans during the pre-contrast injection phase, the dynamic phase during and right after contrast agent injection, as well as the quasi static post-contrast phase. This research will focus on studying the optimal way of encoding the vascular architecture

into the MRI signal and the decoding approach. In addition, the image processing methodology will be optimized. The second part of this study is a proof-of-concept clinical study. This part aims to link the vascular parameters with molecular profiles of tumors by using the collected data for the development of machine learning algorithms for predicting the tumor*s genotype based on its vascular signature.

Study burden and risks

For the first cohort, the additional burden will not be substantial for the participant. The additional scan time will not exceed 10 minutes and therefore the impact on the patient will be limited. For the second and third cohort, the additional burden includes a prolonged MRI examination at a clinical MRI scanner (3T) and an optional additional examination at 7T MRI including additional CA injection. The ultrahigh field 7T MRI system is commonly used for research and no serious adverse events have been reported1. Patients participating in this study will have no personal benefit; their participation aids in the development of a novel MRI method for the non-invasive determination of the tumor*s molecular profile. Moreover, there is a small chance that the additional 7T MRI scan would provide more information on the status of the disease in the participant.

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

Patients scheduled for brain MRI with contrast injection as part of the clinical diagnostic procedure (cohort 1), patients diagnosed with suspected glioma scheduled for brain MRI as part of the clinical diagnostic procedure (cohort 2), patients with (suspected) glioma referred for biopsy or resection (cohort 3).
Age 18 years or older.
Signed informed consent.

Exclusion criteria

Contra-indications for an MRI exam.
Reduced kidney function.
Pregnancy.

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):	06-03-2023
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	Philips Achieva 7T MRI
Registration:	No

Ethics review

Approved WMO Date:	15-09-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05274919
CCMO	NL76929.058.21