Glioblastoma imaging for the detection of tumor progression using amide proton transfer weighted chemical exchange saturation transfer MRI

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Primary Objective:Determine the optimal threshold on APTw-CEST images in a multi-center (4 academic insti-tutes) multi-vendor (Philips, Siemens and GE) clinical trial, to distinguish tumor progression from treatment-related effects. Secondary…

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

Summary

ID

NL-OMON57140

Source
ToetsingOnline

Brief title
GLIMPCE

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: KWF subsidie project 14728

Intervention

Keyword: APTw-CEST, biomarker, Glioblastoma, MRI

Outcome measures

Primary outcome

Threshold on APTw-CEST images that accurately distinguishes between true progression and pseudoprogression in recently treated glioblastoma patients. The accuracy will be optimized using Receiver operating characteristic (ROC) curve analysis and the Youden index.

Secondary outcome

na

Study description

Background summary

A major issue with glioblastoma treatment is the occurrence of contrast enhancement after treatment with radiotherapy or chemoradiotherapy. This enhancement can be due to more tumor growth; called true progression. It can also be due to treatment-related effects; called pseudoprogression. Amide proton transfer weighted (APTw) chemical exchange saturation transfer (CEST) magnetic resonance imaging (MRI) is a technique that indirectly images pro-teins and peptides in a tissue. Because these molecules are overexpressed in tumor tissue, APTw-CEST MRI has been shown to be good at distinguishing between true progression and pseudoprogression, which is important as they require vastly different responses.

This technique shows promise to become an important biomarker in glioblastoma treatment, how-ever it currently lacks standardization, as studies are generally done in one center on MRI machines of one vendor.

This multi-center study will make APTw-CEST MRI a clinically usable biomarker for the de-tection of tumor progression in glioblastoma patients by providing acquisition and post-pro-cessing recommendations, as well as a threshold on

APTw-CEST images that would allow a
clinician to accurately distinguish between pseudoprogression and true progression, regard-less of where the images were acquired and with which system.

The underlying processes that make APTw-CEST a reliable biomarker for glioblastoma treat-ment response evaluation are not clearly known. Using other advanced MRI techniques (dif-fusion, perfusion) and
O-(2-[18F]fluoroethyl-)-L-tyrosine Positron Emission Tomography
(FET-PET), and correlating these images with the APTw-CEST images will give a better in-sight into these processes.

Study objective

Primary Objective:
Determine the optimal threshold on APTw-CEST images in a multi-center (4 academic insti-tutes) multi-vendor (Philips, Siemens and GE) clinical trial, to distinguish tumor progression from treatment-related effects.

Secondary Objective(s):
* Correlate APTw-CEST MRI to complimentary, advanced imaging parameters such as FET-PET, diffusion and perfusion MRI, and Response Assessment for
Neuro-Oncol-ogy (RANO) criteria.
* Provide recommendations for the acquisition and post-processing of APTw-CEST MRI.

Study design

In this prospective cohort study, all clinical MRI scans will be extended with the APTw-CEST protocol. The patient receives their standard care and decisions will be made based on standard-of-care imaging.

The APTw-CEST images and diagnosis from standard follow-up will be used to determine the threshold on APTw-CEST images that would most accurately distinguish between pseudoprogression and true progression early after treatment.

Additional advanced imaging (diffusion, perfusion, FET-PET) taken during the treatment and follow-up of the patient will be used to correlate areas of high APTw signal with other signals.

Study burden and risks

:The clinical care of the patient group will not be altered. The APTw-CEST images will not be used to make any clinical decision. Patients will not have personal benefit from this study, and will have the burden of a prolonged scan

time of 10-15 minutes.

All further imaging used in this study; perfusion, diffusion and FET-PET will not be taken specifically for this study and will only be taken when clinically indicated, except in LUMC where the FET-PET will be added to standard-of-care.

The addition of FET-PET in the patient group in LUMC is warranted as the long-term risks are negligible for this patient group, due to the median survival of 12-14 months.

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

Confirmed diagnosis of glioblastoma based on histopathological or molecular

analysis
of biopsy after surgery, or suspected of glioblastoma based on medical imaging.
• Scheduled to undergo radiotherapy or combined chemo-and radiotherapy
• 18 years and older
• Able to give informed consent.
• Patient will undergo clinically indicated MRIs

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded
participation in this study:
• Inability to give informed consent
• Contraindication for MRI
• Brain pathology affecting CEST contrast, such as a recent stroke or previous
skull
radiotherapy, as determined by the principal investigators (PIs)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-12-2024
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-10-2024

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL86895.078.24