‘Glioblastoma broadband power as a longitudinal biomarker for tumor progression’

No registrations found.

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

Summary

ID

NL-OMON27265

Source
Nationaal Trial Register

Brief title
GOALS2

Health condition

Glioblastoma (GBM)

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

MEG peritumoral BB power,
Radiological/Clinical progression

Secondary outcome

EEG peritumoral BB power,
CEST MRI,
rsfMRI,
questionnaires

Study description

Background summary

Rationale: Glioblastoma (GBM) growth and brain activity are intricately related, but it is unclear how exactly they co-evolve over time. More specifically, we hypothesize that GBM growth (as determined using routine magnetic resonance imaging (MRI) and clinical status) is preceded by increasing brain activity as operationalised with BB power and measured with magnetoencephalography (MEG) and/or electroencephalography (EEG, which might be a cheap and accessible alternative to MEG).

Objective: To investigate the relationship between MEG/EEG brain activity and GBM growth.

Study design: Longitudinal study.

Study population: 100 GBM patients

Main study parameters/endpoints: Main study parameters are (1) MEG/EEG brain activity at different timepoints during the disease, and (2) radiological and clinical markers of tumor growth. As secondary study parameters, we include (1) chemical exchange saturation transfer (CEST) MRI and resting-state functional MRI (rsfMRI) at a number of timepoints.

Study objective

- Hypothesis 1 (H1): MEG peritumoral broadband power is relatively stable in the context of stable disease and pseudoprogression in GBM patients.
- Hypothesis 2 (H2): MEG peritumoral broadband power increases significantly when progression occurs.
- Hypothesis 3 (H3): It is possible to create a cut-off for MEG peritumoral broadband power that yields adequate sensitivity and specificity in determining progression.

Secondary Objective(s):
- Repeat H1-H3 on EEG instead of MEG measures of peritumoral broadband power.
- Investigate the (added) value of chemical exchange saturation transfer (CEST), a protein-sensitive MRI technique that causes a frequency-encoded MR contrast, in determining progression. CEST shows promising initial results to delineate vital tumor without the use of exogenous gadolinium contrast, potentially even earlier than contrast depending methods.

- Investigate whether resting-state functional MRI (rsfMRI), an indirect measure of neuronal activity, may also pertain to GBM progression.

Study design

Maximum 5 time points per subject

Intervention

None

Contacts

Public
AmsterdamUMC - locatie Vumc
Linda Douw

-
Scientific
AmsterdamUMC - locatie Vumc
Linda Douw

-

Eligibility criteria

Inclusion criteria

(1) age > 17 years
(2) histopathologically confirmed GBM
(3) eligible to start the standard treatment of concomitant chemoradiation followed by adjuvant chemotherapy

Exclusion criteria

(1) psychiatric disease or symptoms at the time of inclusion
(2) other comorbidities of the central nervous system, particularly cerebrovascular accidents, multiple sclerosis, Alzheimer’s disease at the time of inclusion
(3) insufficient mastery of the Dutch language,
(4) inability to communicate adequately.

For undergoing the secondary endpoint of additional MRI measurement, patients are excluded when they have contraindications for MRI, but will still be included for the primary endpoints of MEG/EEG and tumor progression.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
After completion of the study, we plan to share derivaties of the IPD, for example MEG and EEG timeseries per brain region of every patient as well as the anonymised clinical information of the patients.

Ethics review

Positive opinion

Date:	21-10-2021
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	NL9817
Other	METC VUmc : METC 2021.0187

Study results