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

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- 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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27265

Bron
NTR

Verkorte titel
GOALS2

Aandoening

Glioblastoma (GBM)

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

MEG peritumoral BB power,
Radiological/Clinical progression

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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.

Onderzoeksopzet

Maximum 5 time points per subject

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

AmsterdamUMC - locatie Vumc
Linda Douw

-

Wetenschappelijk

AmsterdamUMC - locatie Vumc
Linda Douw

-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

(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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	21-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9817
Ander register	METC VUmc : METC 2021.0187

Resultaten