Glioma Oscillatory Activity as a potentiaLly Sensitive biomarker for tumor growth

No registrations found.

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

Summary

ID

NL-OMON20940

Source
Nationaal Trial Register

Brief title
GOALS

Health condition

Glioma

Sponsors and support

Primary sponsor: Amsterdam UMC – Locatie VUmc
Source(s) of monetary or material Support: Cancer Center Amsterdam

Intervention

Outcome measures

Primary outcome

Hypothesis 1: glioma growth and peritumor oscillatory activity
Hypothesis 2: (peritumor) oscillatory activity and NLGN3 expression

Secondary outcome

Not applicable

Study description

Background summary

Glioma is a devastating and lethal type of cancer, which has proven difficult to grasp mechanistically and impossible to treat up to now. Most neuro-oncological research into biomarkers and treatment targets focuses on properties of the glioma itself, to no avail. Recent animal studies showed that glioma growth may be determined by the activity of the surrounding tissue. Higher activity of neurons surrounding a glioma in an animal model causes an acceleration of glioma growth through increased neuroligin-3 (NLGN3) expression. In the current study we evaluate two hypotheses: 1) higher oscillatory activity relates to faster subsequent glioma growth and 2) lower global oscillatory activity of the electroencephalography (EEG), besides magnetoencephalography (MEG), also reflects lower NLGN3 expression of the resected tumor tissue. The first hypothesis will be evaluated in retrospective data of ~50 histopathologically confirmed glioma patients. Tumor growth will be quantified as the difference in tumor size on T1 MRI scans acquired around the MEG recording (t0) and clinical follow up (t1). In grade II and III glioma, this clinical follow up is usually six months, while glioblastoma patients undergo radiological assessment every three months. Peritumor oscillatory activity will be extracted from the MEG using the Automated Anatomical Labeling (AAL) atlas and calculated as broadband power (0.5-48 Hz). To evaluate the second hypothesis, 35 patients with glioma will be included and MEG/EEG registration will be performed within 4-8 weeks after (re)resection. Oscillatory activity will be determined as peritumor (as previously described) and global broadband power. Tissue from each resection will be requested from the pathology department and NLGN3 expression will be semi-quantitatively categorized as low, moderate or high NLGN3 expression after treatment with the primary antibody (mouse monoclonal, ab186307, Abcam, Cambridge, UK) against NLGN3. To test our second hypothesis regression analysis with EEG global oscillatory activity as the dependent variable and NLGN3 expression as the independent variable will be performed, including tumor grade, molecular subtype (if available), presence of epilepsy, and tumor volume at t0 as covariates. The results of the current study can be the first step a larger, international study to evaluate the sensitivity and specificity of oscillatory activity as a biomarker for progression of glioma.

Study objective

1) higher oscillatory activity relates to faster subsequent glioma growth and 2) lower global oscillatory activity of the EEG also reflects lower NLGN3 expression of the resected tumor tissue

Study design

MEG/EEG recording will be performed 4-8 weeks after (re)resection

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

Adults (≥ 18 years), glioma confirmed on radiological assessment and/or histopathology

Exclusion criteria

Psychiatric disease or symptoms, other comorbidities of the central nervous system (particularly cerebrovascular accidents, multiple sclerosis, Alzheimer’s disease), insufficient mastery of the Dutch language, inability to communicate adequately

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:	Recruiting
Start date (anticipated):	03-06-2019
Enrollment:	35
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Fully anonymized primary outcome measures will be shared upon request.

Ethics review

Positive opinion

Date:	03-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55895
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7769
CCMO	NL49485.029.14
OMON	NL-OMON55895

Study results