Linking multimodal network imaging and cognitive functioning in glioma patients

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

Summary

ID

NL-OMON55895

Source
ToetsingOnline

Brief title
Linking multimodal brain networks in glioma patients

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, Glioma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: onderzoekssubsidies (Veni;Branco Weiss Fellowship)

Intervention

Keyword: Brain networks, Cognition, Glioma

Outcome measures

Primary outcome

The main study parameters are MEG, resting-state fMRI, and DTI measures of connectivity and brain network topology.

Secondary outcome

Secundary parameters are:

• Cognitive performance on a standardized neuropsychological test battery and clinical parameters in terms of epilepsy and functional status.

• Several cellular and molecular measurements derived from patients* tumor tissue in the subset of patients undergoing surgery.

• Differences between multimodal neural network measures, and cognitive and clinical parameters derived from the longitudinal measurements.

Study description

Background summary

The brain is the most complex network known to man, which is increasingly studied using tools from network theory. The topology of an *optimal* brain network at every scale includes (1) local clustering combined with overall integration, forming a 'small-world' network, and (2) a hierarchy of larger clusters or modules. In glioma patients, the optimal small-world configuration is disturbed. These changes are not limited to the peritumoral area, but occur brain-wide and relate to cognition and epilepsy. Till now, network studies in glioma are based on functional imaging only. Healthy brains are characterized by high overlap between functional and underlying anatomical network topology in the brain. This congruence might be lost in glioma patients. The investigation of anatomical network topology and its associations with functional connections will add to our understanding of the impact of glioma on

the brain. Furthermore, it will provide neural correlates of patients* symptomatology in terms of epilepsy and cognitive deficits, and may be an intermediate between cellular characteristics of the tumor area and behavior. The longitudinal aspect of this study will elucidate how alterations in the network over time are associated with cognitive and clinical functioning.

Study objective

The current study aims to primarily investigate associations between multimodal networks in glioma patients. Secondary objectives include investigation of the correlations between multimodal neural networks and cognition and epilepsy and linking cellular parameters to these network characteristics. Furthermore, the longitudinal data will elucidate how alterations in mulitmodal neural networks are associated with alterations in cognitive and clinical functioning.

Study design

This is a prospective, cross sectional study with a longitudinal component. The study will be performed at the outpatient clinic of the VU University Medical Center (VUmc). About 275 patients with suspected or confirmed glioma will be included in the coming four years. Anatomical and functional connectivity and network architecture will be measured using magnetoencephalography (MEG), resting-state functional Magnetic Resonance Imaging (rsfMRI) and Diffusion Tensor Imaging (DTI). Patients can be asked to participate in this study more than once.

If patients undergo surgery, tumor tissue will be analyzed for specific tumor markers to correlate cellular characteristics to network properties. This tumor tissue is taken out during clinical routine, which is in no way influenced by this research project. After sufficient tissue is made available for clinical purposes, tumor tissue can be stained for certain particular tumor markers.

Study burden and risks

There are no risks involved with participating in this study.

For patients, the burden associated with participation consists of an extra visit to the outpatients* clinic of the VU University Medical Center. We will try to combine this visit with possible other appointments that patients have, so that we try to avoid an extra visit to the VU University Medical Center. During this visit an MRI scan and MEG measurement will be done, and patients are asked to sit still or lay down while doing nothing further. For most of the patients an MRI scan will not be necessary anymore because this is embedded in the patients' clinical protocol. Furthermore a neuropsychological assessment will be performed. During this part of the study patients' cognitive functioning will be tested by performing several tasks. Prior to this visit

patients receive a questionnaire which can be filled in at home minimizing the burden for patients. This questionnaire takes about 30 minutes. Patients visit the outpatient clinic on a regular bases, so if patients participate more than once we will again try to combine this with possible other appointments to avoid extra visits to the VU University Medical Center. Patients can be asked to participate in this study up to six times, only when patients give consent for this.

In our view, the burden associated with participation is proportionate to the potential value of the research for glioma patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

(1) Adult (>= 18 years).

(2) patients with suspected glioma based on radiological assessment and/or histopathologically confirmed WHO grade II-IV glioma.
(3) written informed consent.

Exclusion criteria

(1) Psychiatric disease or symptoms.
(2) Other comorbidities of the central nervous system.
(3) Insufficient mastery of the Dutch language.
(4) Inability to communicate adequately.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-10-2014
Enrollment:	275
Type:	Actual

Ethics review

Approved WMO Date:	25-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20940
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49485.029.14