

# Neurocognitive functioning and brain plasticity in high-grade glioma patients: a magnetoencephalography pilot

<b>Submission date</b> 23/08/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/10/2007	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NWOpilot01

# Study information

## Scientific Title

### Study objectives

We hypothesise that a relationship is present between functional connectivity, network features and neurocognitive performance in Glioblastoma Multiforme (GBM) patients. We also expect treatment and recurrence of the tumour to lead to remodelling of the neuronosynaptic maps and network features (i.e. plasticity), and hypothesise that these dynamic changes correlate with improvements of cognition.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from ethics boards of two centres participating in the study:

1. Academic Medical Centre (AMC) Medisch Ethische Commissie, received on the 16th July 2007 (ref: MEC 07/134)
2. VU University Medical Center Medical Ethical Board, received on the 12th June 2007 (ref: 2007 /108)

### Study design

Multicentre, observational, case-control study

### Primary study design

Observational

### Secondary study design

Case-control study

### Study setting(s)

Hospital

### Study type(s)

Screening

### Participant information sheet

### Health condition(s) or problem(s) studied

Glioblastoma multiforme, high grade Glioma

### Interventions

Using prospective cognitive data and MEG recordings of ten newly diagnosed glioblastoma multiforme patients and ten glioblastoma multiforme patients with tumour recurrence we will investigate:

1. The impact of tumour- and treatment-related factors on functional connectivity and neural network features, and
2. The correlation between changes in these measures and cognitive function

If such treatment- and/or tumour-related cerebral plasticity and its correlation with cognition can be established in this pilot, future prospective studies will focus in more detail on:

1. The effects of different treatment modalities (e.g. less or more extensive surgery, radiotherapy), and
2. The contribution of tumour-related symptoms (e.g. epilepsy) and their treatment (e.g. anti-epileptic drugs) on neural network function and cognition

This knowledge will eventually assist in the guidance of clinical decision-making in these patients.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Main study parameters are neurocognitive functioning and Magnetoencephalogram (MEG)-measures (synchronisation likelihood and small-world features).

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

01/09/2007

### **Completion date**

01/06/2008

## **Eligibility**

### **Key inclusion criteria**

For newly diagnosed patients:

1. Adult (greater than 18 years)
2. Radiologically suspected GBM prior to surgery
3. Histologically confirmed GBM after surgery
4. Treatment consisting of surgery followed by combined radiotherapy and chemotherapy
5. Written informed consent

For patients with GBM recurrence:

1. Adult (greater than 18 years)
2. Histologically confirmed GBM
3. Treatment consisting of surgery followed by chemotherapy
4. Written informed consent

For matched healthy controls:

1. Adult (greater than 18 years)
2. Written informed consent

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

40

**Key exclusion criteria**

For patient groups:

1. Use of centrally acting drugs, including corticosteroids, other than antiepileptic drugs
2. Psychiatric disease or symptoms
3. Insufficient mastery of the Dutch language
4. Inability to communicate adequately

For controls:

1. Use of centrally acting drugs (including analgesics)
2. Psychiatric disease or symptoms
3. Disorders of the central nervous system
4. Insufficient mastery of the Dutch language

**Date of first enrolment**

01/09/2007

**Date of final enrolment**

01/06/2008

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Department of Medical Psychology, D343

Amsterdam

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1081 BT

**Sponsor information****Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

**Sponsor details**

Department of Medical Psychology  
Amsterdam  
Netherlands  
1081 BT

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.vumc.nl/english/>

**ROR**

<https://ror.org/00q6h8f30>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Vrije University Medical Centre (VUMC) (The Netherlands)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration