ISRCTN73594603 https://doi.org/10.1186/ISRCTN73594603

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

Submission date 23/08/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/08/2007	**Overall study status** Completed	
Last Edited 01/10/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M. Klein

Contact details
Department of Medical Psychology, D343
Vrije University Medical Centre
Amsterdam
Netherlands
1081 BT
+31 (0)20 444 8432
m.klein@vumc.nl

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
Netherlands
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