Cognitive deficits in brain tumor patients after neurosurgery: incidence, severity and prediction of outcome

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON26139

Source
Nationaal Trial Register

Health condition

Primary brain tumor; glioma; meningioma; neurosurgery; objective cognitive functioning; cognitive deficits; neuropsychological impairment

Primaire hersentumor; gliomen; meningeomen; hersenoperatie/neurochirurgie; gezonde controles, objectief cognitief functioneren, cognitieve stoornissen

Sponsors and support

Primary sponsor: St Elisabeth Hospital, Tilburg
Tilburg University
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Changes in objective cognitive functioning from pre-surgery to post-surgery, as measured with a computerized neuropsychological test battery, CNS Vital Signs.

Secondary outcome

Depression, anxiety, subjective cognitive complaints, fatigue, community integration and professional functioning, as measured with the Hospital Anxiety and Depression Scale (HADS), the Cognitive Failures Questionnaire (CFQ), Multidimensional Fatigue Inventory (MFI), Community Integration Questionnaire (CIQ), Work Ability Index (WAI) and Work Limitations Questionnaire (WLQ) respectively.

Study description

Background summary

Deficits in cognitive functions are common in patients with primary brain tumors. These cognitive deficits can be very subtle, and easily go undetected on routine clinical examination. However, they are often very disruptive for a person’s quality of life, preventing return to a normal social and professional life.

Preservation of cognitive functioning is an important outcome measure in glioma surgery, and essential for quality of life. At present, unfortunately, it is largely unknown how surgery affects cognition. A better understanding of the variables that predict the impact of surgery on cognition is of significant importance not only to patients and their families, but also to neurosurgeons. It provides neurosurgeons with evidence-based information about possible individual risk of surgery which will steer clinical decision making and enables to inform patients better about the consequences of surgery on long-term cognitive functioning.

Study objective

Objectives:

1) To describe the incidence and severity of cognitive impairments in patients with glioma and meningiomas before, and 3 and 12 months after surgical treatment.

2) To develop models based on presurgical sociodemographic, clinical, imaging, and (neuro)psychological variables that predict cognitive functioning one year after surgery.

3) To increase knowledge on fatigue, work status, work limitations, and community integration, and their relationship with cognition (over time) in order to improve care for patients with primary brain tumors.

Study design

Patients will complete preoperative (i.e., at the day of hospitalization one day before surgery) neuropsychological tests and questionnaires and will be followed up at 3 and 12 months after surgery. Healthy controls will be tested at the same time points.

Intervention

n/a

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients with supratentorial gliomas and meningiomas undergoing resective surgery in the St. Elisabeth Hospital, Tilburg. Eligible subjects for the control group (recruited from the

general population and matched for age, gender and educational level) should be in good health, with no current or past psychiatric, neurologic, or cognitive disorder, and medication-use that interferes with cognitive function.

Exclusion criteria

Patients and Dutch control subjects will be excluded if 1) they lack of basic proficiency in Dutch, 2) they have an IQ below 85 or low cognitive skills, 3) their Karnovsky Performance Scale is under 60, 4) they are completely unfamiliair with the use of computers, 5) they have an additional (history of) significant neurological or psychiatric disorder, 6) there is a surgery related complication (morbidity or mortality).

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5063
NTR-old	NTR5194
Other	ZonMw Projectnumber; protocol ID MEC : 842003007; NL41351.008.12

Study results

Summary results
Cognitive improvement in meningioma patients after surgery: Clinical relevance of computerized testing. Meskal, I., Gehring, K., van der Linden, S.D., Rutten, G-J.M. & Sitskoorn, M.M. 2015 In: Journal of Neuro-Oncology, 121(3), 617-625