Reducing fatigue, depression, and cognitive deficits with modafinil in low-grade glioma patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25601

Source
NTR

Brief title
N/A

Health condition

fatigue, depression, cognition in low-grade glioma patients

Sponsors and support

Primary sponsor: Department of neurology
VU University Medical Center
P.O. Box 7057
1007 MB Amsterdam
Source(s) of monetary or material Support: NutsOhra zorgsubsidies

Intervention

Outcome measures

Primary outcome

The main study parameters are scores on the CIS, MOS, SF-36, BCM and neuropsychological assessment on the three assessment moments.

Secondary outcome

Secondary study parameter is synchronization likelihood, as measured by MEG.

Study description

Background summary

N/A

Study objective

1. Modafinil influences fatigue, cognitive functioning, and quality of life of LGG patients;

2. There is a correlation between (changes in) fatigue, cognition, and quality of life on the one hand, and functional connectivity in the brains of LGG patients on the other.

Study design

1. Baseline, before treatment;

2. After first 6 weeks of treatment;

3. After second 6 weeks of treatment.

Intervention

Patients will be randomized into two groups. These groups will first receive six weeks of treatment (with either placebo or modafinil), followed by a wash-out period of one week. Hereafter, another treatment period of six weeks will take place, in which patient groups will receive placebo or modafinil respectively (opposite of first treatment). Treatment will begin with 100 mg modafinil, or matching placebo, upon waking and at lunch (200 mg/day). After one week, the dose will be doubled (400 mg/day). If patients experience adverse events at the higher dose, they will be allowed to decrease the medication to the previous dose. Patients will continue at either 200 mg/day or 400 mg/day until the second visit, six weeks after the initial visit.

Contacts

Public
Department of Medical Psychology - D343
VU University Medical Center
M. Klein
Van der Boechorststraat 7
Amsterdam 1081 BT
The Netherlands
+31 20 4448432
Scientific
Department of Medical Psychology - D343
VU University Medical Center
M. Klein
Van der Boechorststraat 7
Amsterdam 1081 BT
The Netherlands
+31 20 4448432

Eligibility criteria

Inclusion criteria

1. Reported severe fatigue (score > 35) on the Checklist Individual Strength (CIS)[51];

2. Histologically proven LGG without signs of tumor recurrence in the last year;

3. Written informed consent.

Exclusion criteria

1. History of chemotherapy treatment;

2. Anti-tumor treatment other than antiepileptic drugs (e.g. chemotherapy, radiotherapy, corticosteroids);

3. Psychiatric disease or symptoms;

4. Insufficient mastery of the Dutch language;

5. Inability to communicate adequately.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009
Enrollment:	64
Type:	Actual

Ethics review

Positive opinion

Date:	11-03-2009
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	NL1623
NTR-old	NTR1721
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Boele, Florien W., et al. "The effect of modafinil on fatigue, cognitive functioning, and mood in primary brain tumor patients: a multicenter randomized controlled trial." Neuro-oncology 15.10 (2013): 1420-1428.