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

Gepubliceerd: 11-03-2009 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25601

Bron
NTR

Verkorte titel
N/A

Aandoening

fatigue, depression, cognition in low-grade glioma patients

Ondersteuning

Primaire sponsor: Department of neurology
VU University Medical Center
P.O. Box 7057
1007 MB Amsterdam
Overige ondersteuning: NutsOhra zorgsubsidies

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline, before treatment;

2. After first 6 weeks of treatment;

3. After second 6 weeks of treatment.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2009
Aantal proefpersonen:	64
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1623
NTR-old	NTR1721
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
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.