TRUE-GRIT: Reducing cognitive impairment in glioma with repetitive transcranial magnetic stimulation and cognitive strategy training

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To investigate the feasibility of a combination therapy (consisting of individualized rTMS and cognitive strategy training) and study measurements in patients with a primary brain tumor during stable disease. The study is considered feasible when 80...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON53811

Source
ToetsingOnline

Brief title
TRUE-GRIT

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC
- Cognitive and attention disorders and disturbances

Synonym
Brain tumor, Glioma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Cancer Center Amsterdam

Intervention

Keyword: cognition, cognitive strategy training, glioma, repetitive transcranial stimulation (rTMS)

Outcome measures

Primary outcome

Feasibility of a combination therapy and study measurements in glioma patients.

Feasibility will be assessed by completed intervention and measurements: how many of the included patients finish the intervention and obligatory measurements at T1.

Secondary outcome

A set of exploratory parameters will be used to investigate the feasibility of measurements aimed at assessing treatment effects in a future RCT. These parameters consist of EMA examining objective and subjective cognitive functioning along the whole study trajectory. Additionally, several measurements will be performed at baseline, directly after and six months after treatment, namely neuropsychological assessments, questionnaires for subjective cognitive functioning, questionnaires concerning quality of life, functioning, fatigue, and psychological wellbeing, neurological examination, advanced neuroimaging and clinical parameters (tumor location, undergone previous treatments, medication use) will be assessed. Additionally, tolerability and side-effects of the rTMS treatment will be assessed.

Study description

Background summary

Up to 80% of glioma patients experience cognitive impairment. These cognitive problems are associated with decreased functional independence and quality of life. A combination therapy consisting of repetitive transcranial magnetic stimulation (rTMS) and cognitive strategy training has potential to reduce cognitive complaints in glioma patients.

Study objective

To investigate the feasibility of a combination therapy (consisting of individualized rTMS and cognitive strategy training) and study measurements in patients with a primary brain tumor during stable disease. The study is considered feasible when 80% of the subjects finish the intervention and obligatory measurements at T1.

Study design

This is a monocenter randomized feasibility study. Patients will be randomized to one of the twotreatment arms: cognitive strategy training + active rTMS or cognitive strategy training + sham rTMS treatment. Measurements will take place at baseline, directly after and six months after treatment. Additionally, around the intervention period patients will have short daily measurements assessed by an app for a period of max. 12 weeks.

Intervention

Patients will receive 7 weeks of combined rTMS/sham + cognitive strategy training (NRMP). 21 sessions of rTMS (3x times a week) and 7 weekly sessions of cognitive strategy training will be given. All patients will receive treatment at Amsterdam UMC location Vrije Universiteit Amsterdam. Besides the treatment sessions in the hospital, patients are asked to do homework assignments for the cognitive strategy training. rTMS will be provided by certified personnel and cognitive strategy training will be given by trained psychologists.

Study burden and risks

Patients will receive 21 sessions of rTMS (30 minutes per session, 3 sessions a week) concurrently to cognitive strategy training (60 minutes per session, 1 session a week). In total, the combination therapy will last for 7 weeks. Assessments will take place before and directly after the treatment and will take approxemately 3 hours. The obligatory measurements consist of neuropsychological assessment, MRI at T0, questionnaires and a daily

measurement via an app on the mobile phone. 6 months after treatment there will be a follow-up measurment consisting of a short neuropsychological assessment and questionnaires. This measurement will approxemately take 2 hours.
Optional measurements are: MEG, MRI at T1 and neurological assessment (approxemately 2,5 hours)

Both rTMS and cognitive strategy training are considered as safe treatments. Potential risks are the possible rTMS-related side effects: TMS is considered safe and generally tolerable. When following the international safety guidelines (Rossi et al. 2021), the risk to induce an epileptic convulsion is extremely low. Hearing protection is achieved by wearing ear plugs during stimulation. There is a lot of experience with rTMS in psychiatric diseases in our team (OA van den Heuvel) and from experience we know that adverse events, or co-occurrences, during treatment in are rare, and consist mostly of headache, local scalp pain and sleepiness. Frequency and severity of these adverse events differs
widely between subjects, and has not led to subjects withdrawing from our earlier trials.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- >= 18 years of age
- Histological diagnosis of diffuse glioma (WHO grade 2,3, or 4)
- Subjective cognitive impairment, defined as CFQ-score >= 44
- Stable disease, i.e. no oncological treatment for <= 2 months prior to inclusion; no radiological progression on the most recent MRI, not older than 6 months, and no clinical progression at inclusion
- Stable dosage (for at least 8 weeks) of anti-epileptic medication

Exclusion criteria

- Current pregnancy or have given birth less than three months ago
- Current other treatment for cognitive complaints
- Karnofsky performance score <70
- A diffuse glioma located in the parietal cortex
- TMS exclusion: implanted medical devices (e.g. pacemaker, deep brain stimulator, cochlear implants, medical infusion device, etc.); metal in the body; dose change in antiepileptic drugs in the last 8 weeks; use of pro-convulsive drugs; substance misuse or withdrawal; sleep deprivation
- MRI exclusion: extreme claustrophobia or metallic objects in or on the body

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2024
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	TMS device - Double 70mm Air Film Coil (MDR-82 study CE-certified)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL82233.018.23