GRASS study: Treating anxiety with CBD in glioma patients

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To investigate the effect of a three-week treatment with cannabidiol (CBD) on anxiety in patients with a primary brain tumor that have no active oncological treatment. Depression, fatigue and general quality of life are secondary outcome...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON20540

Source
NTR

Brief title
GRASS Study

Condition

- Neurological disorders NEC

Synonym
brain tumor

Health condition

glioma or other primary brain tumor patients

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Cancer Center Amsterdam

Intervention

Explanation

Outcome measures

Primary outcome

The primary study outcome is anxiety, as measured with the state-subscale of the state-trait anxiety inventory (S-STAI). Anxiety and distress will also be measured using the hospital anxiety and depression scale (HADS) and the beck anxiety inventory (BAI).

Secondary outcome

Secondary outcomes include: - Depressive complaints - Sleep - Quality of life

Study description

Background summary

Gliomas are primary malignant brain tumors that are incurable to date and lead to a severely reduced quality of life. For these tumors only palliative oncological treatment exist. Due to the short life expectancy, improving quality of life is essential in thesepatients. Many glioma patients currently use non-medicinal cannabinoids for presumed symptom relieve. Cannabidiol (CBD) is freely available in the Netherlands, which presumably leads to this cannabinoid being the most frequently used. Studies are lacking that investigated the effect of cannabinoids on well-being in this population. Consequently, a knowledge gap exists. At present health care providers cannot advice their neuro-oncological patients on the use of cannabinoids nor can they prescribe this medication. The main symptoms during the stable phase disease are fatigue, depressed mood and anxiety.

Study objective

To investigate the effect of a three-week treatment with cannabidiol (CBD) on anxiety in patients with a primary brain tumor that have no active oncological treatment. Depression, fatigue and general quality of life are secondary outcome measures. This study ispart of the GRIP-project, a platform trial to investigate interventions aimed at improving quality of life in patients with brain tumors in five intervention arms.

Study design

A double-blind, placebo-controlled crossover study. Patients will be randomized to 600 mg CBD or placebo as first treatment. CBD or placebo will be administered during three weeks

followed by a washout period of two weeks before the second treatment period starts.

Intervention
Cannabidiol (CBD) - Arvisol

Study burden and risks
The risks for patients participating in this study compromise toxicity from CBD. Most frequently reported adverse effects are drowsiness and fatigue. Liver functions will be monitored as they can increase after CBD use. The questionnaires can be time-consuming and be a burden to patients to some extent. On the other hand, patients will possibly experience a decrease in anxiety, depressive symptoms and an increase in sleep quality and general quality of life. As cannabinoids are currently extensively used by glioma patients, we consider the benefit of filling the existing knowledge gap to outweigh the burden of potential side effects.

Contacts

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Eligibility criteria

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

Inclusion criteria

- diagnosis of primary brain tumor;

- ≥18 years of age;

- moderate to severe anxiety, defined as S-STAI score ≥ 44 at moment of screening;

- ability to understand and sign informed consent in Dutch;

- 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 withinthe most recent two months.

Exclusion criteria

- corticosteroid use, unless in a stable dose ≥ 8 weeks;

- regular cannabis use currently or in past history (≤2 weeks);

- substance abuse (defined as use of hard drugs, or alcohol use more than 3 units per day);

- history of psychosis or anxiety disorder;

- alterations in SSRI/SNRI use or dosage during the prior two months;

- psychological or psychiatric treatment during the prior two months aimed at anxiety;

- current pregnancy or have given birth less than three months ago;

- currently breastfeeding;

- KPS ≤70;

- uncontrolled hyperthyroidism;

- severe liver disorders (AST, ALT and/or gamma-GT more than three times the upper limit);

- severe kidney disorders (eGFR≤30).

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2022
Enrollment:	55
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	07-07-2021
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 54278

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9623
CCMO	NL76031.029.21
EudraCT	2020-004294-48
OMON	NL-OMON54278

Study results