Cannabidiol enhancement of exposure therapy in patients with phobias.

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

Samenvatting

ID

NL-OMON28305

Bron
Nationaal Trial Register

Aandoening

Phobic anxiety disorders, fobische angststoornissen

Ondersteuning

Primaire sponsor: Utrecht University
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure will be the fear questionnaire (FQ, Marks and Mathews 1979).

Toelichting onderzoek

Achtergrond van het onderzoek

Phobic anxiety disorders are among the most prevalent disorders. The estimated lifetime prevalence is estimated at 19%. Also the estimated health care costs are high: 42 billion dollars in the USA annually. Antidepressants and cognitive behavioural therapy are effective but a substantial patient group shows insufficient improvement due to these standard treatments.
Research has yielded solid evidence that the cannabinoid system in the brain is involved in the modulation of anxiety. Specifically, it seems to be influencing extinction of conditioned fear responses. An advantage of cannabidiol as opposed to cannabis (with THC) is that it doesn't produce the 'high' feeling what THC (on itself or as part of cannabis) does. Patients possibly can benefit from the anxiolytic effect of cannabidiol. Cannabidiol is administered preceding cognitive behavioural therapy with exposure (exposure to a feared stimulus). If cannabidiol is found to be effective it might lead to adjustment of the guidelines.

Doel van het onderzoek

The aim of this research project is to investigate cannabidiol as a new medicine to target the cannabinoid system in the reduction of anxiety disorder symptoms. The research question is whether cannabidiol, as an augmentation strategy of exposure therapy in patients with phobic disorders (panic disorder with agoraphobia and social phobia), can speed up and/or increase the magnitude of change due to behavior treatment. We specifically want to target those subjects in whom previous treatment as usual (with SSRIs and/or psychotherapy) has not yielded in sufficient response to treatment, since it is this group that needs treatment enhancement most and therefore may benefit most from treatment enhancement with cannabidiol.

Onderzoeksopzet

Baseline, 1st to 8th treatment, mid-treatment (week after 5th treatment), post-treatment (week after 8th treatment), follow up at 3 and 6 months

Onderzoeksproduct en/of interventie

Cannabidiol (capsule) or placebo (capsule), in combination with exposure therapy with response prevention (ERP)

Contactpersonen

Publiek

Heidelberglaan 1

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Wetenschappelijk

Heidelberglaan 1

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients will be invited to participate when they fulfill the diagnoses mentioned here-above, and provided that they have not or only partially responded to evidence-based treatment (either a full treatment with an SSRI (at least 12 weeks of sufficient dose) and/or at least 10 sessions of cognitive behavioural therapy) in the year preceding referral to the outpatient clinics.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with co-morbid severe psychiatric disorders diagnosed with the SCID-I (severe major depressive or bipolar disorder, psychosis, dependence of alcohol and drugs), with mental deficiency (IQ<80) or inability to adequately read or speak Dutch will be excluded (assessed using a neuropsychological Test (NLV; Schmand et al. 1992), as well as persons with (a history of) epilepsy or brain damage, renal or liver abnormalities, and a history of allergies to medication (adverse reactions or rash).
Regular use of benzodiazepines and of antipsychotics will be an exclusion criterion, contunued use of SSRIs will be permitted, provided that dosages are kept constant during the study. Lastly pregnant or breastfeeding women will be excluded from the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2015
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2015
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	NL4846
NTR-old	NTR5100
Ander register	: ZonMW protocol nr. 40-41200-98-9269

Resultaten