High-dose baclofen for the treatment of alcohol addiction.

Gepubliceerd: 29-10-2012 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON22245

Bron
Nationaal Trial Register

Aandoening

alcohol dependence (AD)

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum (AMC)
Overige ondersteuning: Amsterdams Fonds voor Verslavingsonderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is abstinence, measured in time to the first relapse.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksopzet

1. Baseline (prior to start of the intervention);

2. During intervention (26 days after start);

3. After the end of the intervention (16 weeks after baseline);

Outcome measures are assessed with questionnaires.

Onderzoeksproduct en/of interventie

In this study baclofen or placebo will be orally administered for the duration of 16 weeks. Participants will be included in one of the three groups: A high-dose baclofen group, a low-dose baclofen group or a placebo group.

27-jan-2015 Changes: Since less participants than expected could be included, it was decided to exclude the low-dose baclofen groep and continue with two arms: the placebo group and the high-dose baclofen group.

Contactpersonen

Publiek

-
- -
[default]
The Netherlands
-

Wetenschappelijk

-
- -
[default]

The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male and Female patients, aged between 18-60 years;

2. Participants have a current DSM-IV diagnosis of alcohol dependence;

3. Participants sign a witnessed informed consent;

4. Participants have a breath alcohol concentration lower than 0.5 % at the screening visit;

5. Participants must have been drinking ≥ 14 drinks (female) or ≥ 21 drinks (males) on average per week over a consecutive 30-day period in the 90-day period prior to the start of the study and have two or more days of heavy drinking (five drinks females, six drinks males) in the 90-day period prior to the start of the study;

6. Participants must have had a minimum of 96 hours of abstinence prior to the start of the medication;

7. Participants can be abstinent for a maximum of 21 days prior to the start of the study;

8. Participants must be able to speak and understand Dutch;

9. Participants provide an identified person that can be contacted during the study in the event of loss of contact and can give information about the patient’s alcohol use.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Participants with current severe psychiatric disorders (schizophrenia, schizoaffective disorder,bulimia/anorexia, or ADHD requiring medication) besides depression, bipolar disorder and anxiety;

2. Participants with serious medical illnesses (Parkison’s disease, gastric ulcer, duodenal ulcer, cerebrovascular disease, respiratory insufficiency, hepatic or renal insufficiency, and epilepsy);

3. Patients who are treated with anti-hypertensive medication;

4. Participants who are at risk of suicide evaluated by the suicidality module of the M.I.N.I.;

5. Participants who have a cognitive impairment which is likely to interfere with the understanding of the study and its procedures;

6. Participants with a diagnosis of dependence on any drugs except for nicotine, cannabis, alcohol and caffeine, if alcohol dependence doesn't represent the main addiction;

7. Participants who are/or could be pregnant or nursing infants;

8. Participants who intend to engage in additional treatment for alcohol-related problems. Self-help treatments are not considered formal treatment;

9. Participants with current or recent (3 months prior to the start of the study) treatment with anti-craving medication (acamprosate, naltrexone, disulfiram, or topiramate);

10. Participants who have had more than seven days of inpatients treatment for substance use disorder in the 30 days prior to the start of the study;

11. Participants who have prior use of baclofen in the last 30 days.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-11-2012
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-10-2012
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	NL3519
NTR-old	NTR3681
Ander register	METC : 2012_054 / 2011-004142-17
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A