High-dose baclofen for the treatment of alcohol addiction.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22245

Source
Nationaal Trial Register

Health condition

alcohol dependence (AD)

Sponsors and support

Primary sponsor: Academisch Medisch Centrum (AMC)
Source(s) of monetary or material Support: Amsterdams Fonds voor Verslavingsonderzoek

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Key secondary outcome measures are the total alcohol consumption and the number of heavy drinking days.

Other secondary outcome measures are craving, depression, anxiety, side effects and biological markers.

Study description

Background summary

N/A

Study objective

N/A

Study design

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.

Intervention

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.

Contacts

Public

-
- -
[default]
The Netherlands
-

Scientific
-
- -
[default]
The Netherlands
-

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2012
Enrollment:	160

Type: Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 29-10-2012

Application type: First submission

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
NTR-new	NL3519
NTR-old	NTR3681
Other	METC : 2012_054 / 2011-004142-17
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A