Effects of long-term treatment with modafinil on relapse and impulse control in alcohol dependence.

No registrations found.

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

Summary

ID

NL-OMON20456

Source
Nationaal Trial Register

Brief title
TrIP - RCT

Health condition

Alcohol dependent patients and/or polysubstance abusers with alcohol addiction as the primary problem

Sponsors and support

Primary sponsor: - Amsterdam Medical Center; Amsterdam Institute for Addiction Research (AMC; AIAR),
- University of Antwerp; Collaborative Antwerp Psychiatric Research Institute (UA; CAPRI)
- Psychiatric Centre Alexian Brothers (Boechout; Belgium)
Source(s) of monetary or material Support: ZonMw - programme risk behavior and substance dependency

Intervention

Outcome measures

Primary outcome

1. Test performance (on both neurocognitive tests and self-report questionnaires);

2. Craving ratings;

3. Relapse (in terms of quantity/frequency measures of alcohol use).

Secondary outcome

Improvement or deterioration of specific characteristics (such as depression, ADHD symptoms, anhedonia, fatigue), due to the intervention of modafinil.

Study description

Background summary

There is growing evidence that cognitive deficits play an important role in the development, course and relapse of substance abuse disorders. In particular, functions that involve control over one's own behavior (impulsivity), and over behavior when confronted with motivationally relevant drug cues (craving) are related to relapse in recent studies. Because pharmacological manipulations of cognitive deficits are rare and relapses after treatment are the rule rather than the exception, we will present a randomized, double-blind, placebo-controlled trial with modafinil, a known cognitive enhancer and wake-promoting agent. Hundred alcohol dependent patients will be randomized to a single morning dose of modafinil (300mg/d), or matching placebo, for 10 weeks. Both neurocognitive tests (on impulsivity and overall cognitive functioning) and self-report questionnaires will be administered before, during and after treatment. Patients will be followed up 6 months after treatment, to measure relapse rate. Primary outcome variables are test performance, craving ratings and relapse. It is expected that modafinil improves cognitive functioning, increases time to first relapse and reduces relapse rates and relapse severity. In addition, DNA samples will be taken to investigate different polymorphisms associated with addiction and impulsivity. It is expected that participants with different genotypes will be affected differently by modafinil.

Study objective

It is expected that modafinil improves cognitive functioning in abstinent alcohol dependent patients, increases time to first relapse and reduces relapse rates and relapse severity. In addition, it is expected that participants with different genotypes will be affected differently by modafinil.

Study design

Both neurocognitive and self-report questionnaires will be administered:

1. Before treatment (= baseline measurement);

2. During treatment (after at least one week of a fixed dose of medication/placebo);

3. After treatment (= after 10 weeks of treatment AND testing at least one week after cessation of medication/placebo).

Follow-up: 3 and 6 months after cessation of treatment with modafinil.

Intervention

MODAFINIL GROUP:

1. 300mg/day;

2. Single dose;

3. Oral administration;

4. (3 x 1 tablet of 100mg/day) during 10 weeks.

Adminstration scheme:

1. Day 1-5 : 100mg/day;

2. Day 6-10: 200mg/day;

3. Day 11-70: 300mg/day.

CONTROL GROUP:

1. Placebo tablets, containing lactose (3 x 1 tablet);

2. Comparable administration and administration scheme as the modafinil group.

Contacts

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Eligibility criteria

Inclusion criteria

1. Current DSM-IV diagnosis of alcohol dependence, but recently detoxified and abstinent and not using benzodiazepines for a least one week;

2. 18-60 years;

3. Male/female;

4. Signed informed consent;

5. Following the behavioural treatment programme.

Exclusion criteria

1. Illiteracy - restricted knowledge of Dutch;

2. Mental retardation (IQ < 75);

3. Colour blindness;

4. Current use of prescription or illicit psychoactive drugs;

5. Lifetime history of head injury with loss of consciousness for more than 5 minutes;

6. Serious neurological or psychiatric disorders (e.g. psychosis, dementia, bipolar disorder, antisocial personality disorder, major depressive disorder, anxiety disorder, sleep disorder);

7. Being on an active low-calorie diet (<1000 calories/day);

8. Being pregnant, planning to become pregnant, or breast feading;

9. Unstable medical illness (e.g. hypertension, diabetes, myocardial infarct).

With respect to modafinil:

1. Use of medication affecting the central nerve system (e.g. benzodiazepines, anti-depressants,...);

2. Hypersensitivity for modafinil and lactose;

3. Any disease of the gastrointestinal system, liver or kidneys.

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):	07-01-2009
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	25-03-2009
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	NL1638
NTR-old	NTR1736
Other	Projectnumber ZonMw – programme risk behavior & substance dependency : 31160003
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A