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

Gepubliceerd: 25-03-2009 Laatst bijgewerkt: 13-12-2022

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...

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

Samenvatting

ID

NL-OMON20456

Bron
Nationaal Trial Register

Verkorte titel
TrIP - RCT

Aandoening

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

Ondersteuning

Primaire 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)
Overige ondersteuning: ZonMw - programme risk behavior and substance dependency

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Leen Joos
Universiteit Antwerpen, CAPRI, CDE R3.21
Universiteitsplein 1

Wilrijk 2610
Belgium
+32 (0)3 820 24 17

Wetenschappelijk

Leen Joos
Universiteit Antwerpen, CAPRI, CDE R3.21
Universiteitsplein 1

Wilrijk 2610
Belgium
+32 (0)3 820 24 17

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-01-2009
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A