A prospective, double-blind, placebo-controlled trial investigating the efficacy and safety of Org 25935 in relapse prevention in subjects with alcohol dependence

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Primary objective- To assess the effects of Org 25935 on heavy drinking in subjects with alcohol dependence.Secondary objectives- assess the effects of Org 25935 on the amount of drinking- To assess the effects of Org 25935 on the first relapse to...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33955

Source
ToetsingOnline

Brief title
OH-D

Condition

- Other condition
- Psychiatric disorders NEC
- Lifestyle issues

Synonym
alcohol dependence, alcoholism

Health condition

toelichting psychische stoornissen: alcoholisme, alcoholafhankelijkheid valt in MedDRA ook onder psychiatrische stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough
Source(s) of monetary or material Support: farmaceutische industrie;door de opdrachtgever van dit onderzoek;zie sectie B5/6.

Intervention

Keyword: alcoholism, dependence, prevention, relapse

Outcome measures

Primary outcome

• Percentage of days of relapse into heavy drinking

Secondary outcome

• Number of drinks per heavy drinking day

• Number of drinks per drinking day

• Percent of abstinent days

• Percent of complete abstinence

• Number of relapses

• Number of lapses

• Cumulative number of no or non-heavy drinking days

• Time to first relapse into heavy drinking

• Time to first drink

• Obsessive Compulsive Drinking Scale

• Visual Analogue scale

• Clinical Global Impression

• Number of responders

• Alcohol marker

Study description

Background summary

Alcohol dependence is a widespread and debilitating disorder which places a tremendous burden on society in terms of healthcare costs, lost wages, and personal sufferings.
In addition to social support and behavioral therapy, there are at present three compounds approved for the treatment or management of relapse prevention in alcohol dependence: disulfiram, naltrexone and acamprosate. Both naltrexone and acamprosate improve outcome in rehabilitation of alcohol-dependent patients, but seem to act on different aspects of drinking pathology.
There is increasing evidence that drug-induced changes in glutamatergic neurotransmission might play a role in the development of alcoholism. Modulators of the glutamatergic/NMDA receptor system are now considered in the search for pharmacotherapeutic agents that may be useful in the treatment of alcohol dependence. Org 25935 is a glycine reuptake inhibitor that functions as a modulator of this system.

Study objective

Primary objective
- To assess the effects of Org 25935 on heavy drinking in subjects with alcohol dependence.

Secondary objectives
- assess the effects of Org 25935 on the amount of drinking
- To assess the effects of Org 25935 on the first relapse to heavy drinking
- To assess the effects of Org 25935 on abstinence
- To assess the safety and tolerability of Org 25935
- To explore potential predictors of response to Org 25935

Study design

This trial will be a prospective, double-blind, randomized parallel group comparison of
12 mg b.i.d. Org 25935 and placebo b.i.d.
Subjects who underwent a detoxification program (as part of the standard treatment procedure of alcohol dependent subjects who seek help for reducing their alcohol use) and fulfilling the selection criteria will be enrolled in

the trial after signing an informed consent. The treatment period will be 12 weeks.

Intervention

12 mg b.i.d. Org 25935 or placebo b.i.d.

Study burden and risks

Discomforts mainly exist of experience of side effects (i.e. dizziness, anxiety, headache, somnolence, and lethargy, visual disturbance and vision blurred) which seem to be relatively mild, transient, and resolving without intervention. The study-related activities comprise 13 visits to the clinic for various interviews, questionnaires, blood and urine sampling, alcohol breath tests, ECG, and ophthalmologic tests. Subjects may or may not receive a direct therapeutic benefit as a result of being in this study.
The subjects will get extensive health check-ups, guidance of compliance, a lot of information and a compensation for travel, time and possible discomforts.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Diagnosis of alcohol dependence - meeting at least 5 out of 7 criteria according to DSM-IV-TR specifier;one of which should be criterion 1 (tolerance) or 2 (withdrawal);
•Primary complaints according to Mini-International Neuropsychiatric Interview (MINI) should be alcohol problems;
•Subjects must have gone through a detoxification program, have a clearly stated desire to stay abstinent and present at baseline with the following: be alcohol abstinent for at least 3 days, benzodiazepine free for at least 3 days, and a Clinical Institute Withdrawal Assessment (CIWA) score < 10;
•Age 18-65 years at screening;
•BMI > 16 kg/m^2;
•Breath alcohol concentration < 0.02% (at screening and baseline)
•Male or female (not of childbearing potential, or not pregnant, non-lactating and using adequate contraception)

Exclusion criteria

•Subjects requiring pharmacological treatment for a primary diagnosis of major depressive disorder, anxiety, panic disorder or social phobia;
•Subjects with psychotic disorders (according to MINI);
•Subjects with a medium or high suicidality risk (as assessed by MINI)
•Active substance abuse (resulting in either physical or mental damage as defined by ICD10) or dependence other than alcohol (excluding nicotine) within 12 months prior to screening, e.g. cannabis, benzodiazepine, amphetamines, chlo(r)methiazole, opiates, cocaine, hallucinogens or other substances;
•Use of one of the following drugs during the last 14 days prior to screening: cannabis, amphetamines, opiates, cocaine, hallucinogens;
•Use of any medication that can have an effect on alcohol consumption within 30 days of study initiation, including naltrexone, acamprosate, disulfiram, ondansetron, topiramate, SSRIs, mirtazapine, varencicline, gabapentin, levetiracetam;
•A clinically relevant visual disturbance, such as cataract, color blindness, macular degeneration, glaucoma or retinal disease;
•Untreated or uncompensated clinically significant renal, endocrine, hepatic, respiratory, cardiovascular, hematological, immunological or cerebrovascular disease, malignancy, or other chronic and/or degenerative process at screening;
•Any clinically meaningful abnormal laboratory, vital sign, physical examination or ECG finding which, in the opinion of the investigator, may interfere with the interpretation of

safety or efficacy evaluations;
•QTc interval (Fridericia corrected) at screening >450 ms (male), >470 ms (female);
•Serious neuropsychiatric condition that can impair judgment or cognitive function (including dementia or amnestic disorder) to an extent that providing informed consent or complying with treatment is precluded;
•History or present evidence of epileptic disorders or withdrawal seizures;
•History of substance withdrawal delirium;
•Breast-feeding woman, or a positive result of urine pregnancy test (at screening), or plan to become pregnant during the course of the trial (females only);
•Pending legal charges with the potential for incarceration, probation, or parole;
•Homelessness (less than 2 months stable residence);
•Participation in a clinical trial during the three months prior to screening.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-03-2009
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-03-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-06-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-05-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2008-005318-35-NL
ClinicalTrials.gov	NCT00764660
CCMO	NL25322.040.09