ISRCTN74707125 https://doi.org/10.1186/ISRCTN74707125

Does Acamprosate Decrease Cue-induced Alcohol Craving?

Submission date	Recruitment status	[ ] Prospectively registered
13/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2008	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-004514-17

Protocol serial number
EudraCT number:

Study information

Scientific Title

A randomised placebo-controlled trial of acamprosate effects on alcohol cue reactivity and alcohol priming in dependent patients

Acronym
DADCAC

Study objectives
1. Acamprosate attenuates cue-induced subjectively experienced and physiolological correlates of craving
2. Acamprosate attenuates alcohol-induced subjectively experienced and physiolological correlates of craving

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial was approved by:
1. The Regional Ethical Review Board in Stockholm on the 23rd March 2005 (ref: 2005/30-31/3)
2. The Swedish Medical Products Agency on the 5th April 2005 (EudraCT number: 2004-004514-17)

Primary study design
Interventional

Study design
The study used a randomised, double blind, single-site, placebo-controlled design comparing cue- and alcohol-induced craving for acamprosate and placebo treated patients

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Alcohol dependence

Interventions
Patients were assigned to 22 days of either acamprosate (1998 mg/day) or placebo treatment according to a randomisation process conducted by the Karolinska University Hospital pharmacy. Medication (150 tablets containing 333 mg acamprosate or placebo) was dispensed once per patient, at the start of the trial, with instructions to intake 6 tablets per day (2 in AM, 2 midday, 2 in PM).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Acamprosate

Primary outcome(s)

1. The difference in subjectively experienced craving post exposure to non-alcohol related stimuli versus alcohol related stimuli
2. The difference in subjectively experienced craving between pre- and post-consumption of an alcoholic drink

For both measures comparisons are made between acamprosate versus placebo treated patients. Measures are collected post 22 days of treatment. Patients then come to the clinic and go through a series of sessions where they are exposed to alcohol versus non-alcohol related stimuli, and also take part in a alcohol priming paradigm. Present alcohol craving is measured in connection to each exposure.

Key secondary outcome(s)
Physiological measures of craving:
1. Pulse
2. Blood-pressure
3. Cortisol in blood
4. Galvanic skin response
5. Skin temperature

Measures are collected post 22 days of treatment. Patients then come to the clinic and go through a series of sessions where they are exposed to alcohol versus non-alcohol related stimuli, and also take part in an alcohol priming paradigm. Present alcohol craving is measured in connection to each exposure.

Completion date
05/02/2007

Eligibility

Key inclusion criteria
1. A male or a non-pregnant/non-nursing female between 18 and 65 years of age
2. A goal of controlled drinking
3. An intact sense of smell
4. Fulfilling the criteria for alcohol dependence according to Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)
5. Willingness to give informed consent and comply with study procedures
6. Alcohol consumption in 15 of the last 90 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Key exclusion criteria
1. Seeking complete alcohol abstinence
2. Current use of any medication that interferes with salivation
3. A diagnosis of an Axis I psychiatric disorder according to DSM-IV criteria (including all forms of substance dependence other than nicotine and alcohol)
4. A current use of psychoactive medications to manage schizophrenia, bipolar disorder, or major depression
5. Inpatient alcohol detoxification within the last 4 days
6. Acamprosate medication during the last year
7. Use of illegal drugs during the course of the study

Date of first enrolment
01/09/2005

Date of final enrolment
05/02/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Clinical Neuroscience
Stockholm
Sweden
17176

Sponsor information

Organisation
Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

ROR
https://ror.org/04g380834

Funder(s)

Funder type
Research organisation

Funder Name
AFA insurances (AFA försäkringar) (Sweden) - http://www.afaforsakring.se

Funder Name
Systembolagets Council for Alcohol Research (Systembolagets råd för alkoholforskning) (Sweden) - http://www.can.se/sa/node.asp?node=1663

Funder Name
Milan Valverius Foundation (Sweden) - http://www.salusansvar.se/info/default.aspx?FolderID=3063a24d-26b2-416d-b00a-1d4d06810b2e

Funder Name
Foundation for Research on Psychiatric Diseases (Psykiatrifonden) (Sweden) - http://www.psykiatrifonden.se

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration