

# Does Acamprosate Decrease Cue-induced Alcohol Craving?

<b>Submission date</b> 13/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2008	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**  
2004-004514-17

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
EudraCT number: 2004-004514-17

# 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 physiological correlates of craving
2. Acamprosate attenuates alcohol-induced subjectively experienced and physiological 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)

## 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

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/09/2005

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

56

**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)

## Sponsor details

Box 17914  
Stockholm  
Sweden  
118 95

## Sponsor type

Hospital/treatment centre

## Website

<http://www.beroendecentrum.com>

## 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 (Psykiatricifonden) (Sweden) - <http://www.psykiatricifonden.se>

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration