

# A double-blind, placebo-controlled parallel-group pilot study of the effectiveness of D-cycloserine in reducing craving during cue-exposure therapy in abstinent alcohol-dependant subjects

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/09/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N0038174882

# Study information

## Scientific Title

## Study objectives

Can D-cycloserine improve extinction of cue-induced craving in alcohol dependence?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Double-blind placebo-controlled parallel-group pilot study

## Primary study design

Interventional

## Study type(s)

Not Specified

## Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Alcohol dependence

## Interventions

RCT: [A] D-cycloserine; [B] placebo.

Screening visit: medical and psychiatric history, physical exam, biochemistry and haematology, liver function, drugs of abuse screen and ECG. Personality Questionnaire - TPQ and EPQ, Severity of Alcohol Dependence questionnaire and a semi-structured consumption of alcohol questionnaire. Instruction given for a standardised breakfast on the testing days. Modified Stroop test given.

Test day 1: Baseline blood pressure and heart rate recordings, urine screen for drugs of abuse, breath alcohol determination and subjective ratings obtained from breakfasted participants. Participants complete outcome measures. After medication, graded cue exposure when peak plasma level reached.

Test Day 2: as Test Day 1

Test Day 3: as test day 1 but no medication given to either group.

## Intervention Type

Drug

## Phase

Not Specified

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

D-cycloserine

**Primary outcome(s)**

Spielberger State and Trait Anxiety Inventory, Beck Depression Inventory, OCDS. Alcohol Urge Questionnaire, and visual analogue scores to rate craving and mood.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

24/04/2009

**Eligibility****Key inclusion criteria**

24 abstinent alcohol dependant males who attend the Bristol Area Specialist Alcohol Service. 12 in each group, D-cycloserine and placebo

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Male

**Key exclusion criteria**

1. Substance misuse or dependence (other than alcohol)
2. Major psychiatric morbidity such as psychosis
3. Clinically significant abnormality on physical examination or investigation
4. Pregnancy or breast feeding
5. Taking acamprosate, disulfiram or naltrexone

**Date of first enrolment**

19/12/2005

**Date of final enrolment**

24/04/2009

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Psychopharmacology Unit**  
Bristol  
United Kingdom  
BS1 3NY

## Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

## Funder(s)

### Funder type

Government

### Funder Name

Avon and Wiltshire Mental Health Partnership NHS Trust (UK), NHS R&D Support Funding

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2011		Yes	No