

# 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

**Contact name**  
Prof David Nutt

**Contact details**  
Psychopharmacology Unit  
Dorothy Hodgkin Building  
Whitson Street  
Bristol  
United Kingdom  
BS1 3NY  
david.j.nutt@bristol.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

19/12/2005

### **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

### **Age group**

Not Specified

### **Sex**

Male

### **Target number of participants**

24

### **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**

England

United Kingdom

**Study participating centre**

Psychopharmacology Unit

Bristol

United Kingdom

BS1 3NY

## **Sponsor information**

**Organisation**

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

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Government

## Funder Name

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

# 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

## Study outputs

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