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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

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/09/2012	Mental and Behavioural Disorders	

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

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
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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?
Results article	results	01/07/2011		Yes	No