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D-cycloserine-supported exposure in patients with panic disorder

Submission date	Recruitment status	[ ] Prospectively registered
01/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/03/2017	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Agoraphobia is a fear of being in situations where escape might be difficult or that help wouldn't be available if things go wrong. It usually develops as a complication of panic disorder, an anxiety disorder involving panic attacks and moments of intense fear. Agoraphobia can be treated with cognitive behavioural therapy (CBT), a talking therapy that can help patients manage their problems by changing the way they think and behave. CBT uses a type of therapy called exposure therapy, which involves being gradually exposed to the feared situation and using relaxation techniques and breathing exercises to help reduce anxiety. The aim of this study is to find out whether exposure therapy can be improved with the use of the drug D-cycloserine.

Who can participate?
Patients age 18-75 with panic disorder and agoraphobia

What does the study involve?
All participants undergo CBT consisting of eight group sessions within 1 month plus three individual exposure therapy sessions. One hour before the start of each exposure session, participants are randomly allocated to receive either D-cycloserine or a placebo (dummy drug). Panic and agoraphobia symptoms are measured at the start of the study, at the end of therapy (1 month after the start of the therapy), and at 2 and 6 months after the start of the therapy.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Charite - Universitatsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
October 2007 to April 2009

Who is funding the study?
Federal Ministry for Education and Research (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2006-004860-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006-004860-29

Study information

Scientific Title
D-cycloserine-supported exposure in patients with panic disorder

Acronym
Panik-Cyclo

Study objectives
Administration of D-cycloserine supports the therapeutic effect of exposure therapy in patients with panic disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Ausschuss 4 der Ethikkommission des Landes Berlin), 03/01/2007, ref: EK 5 618/06

Study design
Double-blind randomised placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Panic disorder with agoraphobia

Interventions
All patients will undergo cognitive behavioural therapy consisting of eight group sessions (group size: 4-8) within one month plus three individual exposure therapy sessions in a standardised procedure. One hour before start of each exposure session, half of the patients will receive 50 mg of D-cycloserine orally, and half of the patients will receive a placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
D-cycloserine

Primary outcome measure
Panic and Agoraphobia Scale, measured at baseline, at the end of therapy (one month after start of the therapy), 2 months after start of therapy, 6 months after start of therapy.

Secondary outcome measures
1. Mobility Inventory for Agoraphobia
2. Beck Depression Inventory
3. Beck Anxiety Inventory
3. Hamilton Rating Scale for Depression

4. Hamilton Rating Scale for Anxiety
5. Clinical Global Impression

Outcomes will be measured at baseline, at the end of therapy (one month after start of the therapy), 2 months after start of therapy, 6 months after start of therapy.

Overall study start date
01/10/2007

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Subject familiarised with experimental procedure and had given written informed consent according to AMG §40(1)3b
2. Diagnosis of panic disorder with agoraphobia, at least "moderately ill"
3. Age: 18-75 years
4. Sufficiently able to communicate with investigator, answer questions and fill in questionnaires
5. If pre-menopausal female: negative pregnancy test and safe contraception during study period
6. Reachability of patient for treatment and follow-up
7. Compliance of patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
44

Key exclusion criteria
1. Known overreaction to D-cycloserine
2. Hospitalisation in a mental institution according to AMG §40(1)4
3. Other psychiatric illnesses like schizophrenia, substance abuse or dementia
4. Acute suicidal tendency
5. Epilepsy or other illness of the central nervous system (CNS) (e.g. brain tumour, encephalitis)
6. Severe medical illness like severe hypertension, severe cardiac insufficiency, condition after acute myocardial infarction, cardiac arrhythmia of severity index IV or V according to Lown

grade, severe dysfunction of liver or kidney, diabetes mellitus requiring insulin treatment, disturbances of haematopoiesis
7. Pregnancy or breastfeeding
8. Changes of psychopharmacological treatment within the last eight weaks or discontinuation of psychopharmacological treatment within less than four weeks before beginning of the study
9. Recent interference with diurnal cycle

Date of first enrolment
01/10/2007

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Germany

Study participating centre
Charite - Universitatsmedizin Berlin
Berlin
Germany
10117

Sponsor information

Organisation
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

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Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung (ref: 01GV0612)

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	01/08/2011		Yes	No