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Association of the neuroendocrine parameters of cortisol and adrenocorticotropin hormone (ACTH) during repeated exposure therapy with long-lasting therapy outcome in patients with panic disorder and agoraphobia

Submission date	Recruitment status	[ ] Prospectively registered
12/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/08/2019	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
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Association of the neuroendocrine parameters of cortisol and adrenocorticotropin hormone (ACTH) during repeated exposure therapy with long-lasting therapy outcome in patients with panic disorder and agoraphobia: an observational study

Study objectives
During exposure, patients will release higher concentrations of stress hormones compared to controls. Concentrations of stress hormones during exposure will be related to therapy outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Ethikausschuss 1 am Campus Charité - Mitte, Berlin, Germany) approved on the 6th February 2007 (ref: EA1/199/06)

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Panic disorder with agoraphobia

Interventions

Eight sessions of standardised and manualised cognitive behavioural group-therapy for panic disorder and agoraphobia plus three individual exposure therapy sessions employing flooding technique, were administered. Before, during and after exposure therapy, blood samples were drawn via an indwelling catheter from each patient.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Concentrations of cortisol and adrenocorticotropin hormone (ACTH) during exposure training
2. Panic and Agoraphobia Scale after therapy and at follow-up

Secondary outcome measures
1. Mobility Inventory for Agoraphobia after therapy and at follow-up
2. Beck Depression Inventory after therapy and at follow-up
3. Beck Anxiety Inventory after therapy and at follow-up
4. Hamilton Rating Scale for Depression after therapy and at follow-up
5. Hamilton Rating Scale for Anxiety after therapy and at follow-up
6. Clinical Global Impression after therapy and at follow-up

Overall study start date
01/03/2007

Completion date
01/03/2008

Eligibility

Key inclusion criteria
1. Subject familiarised with experimental procedure and had given written informed consent
2. Diagnosis of panic disorder with agoraphobia according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV), at least "moderately ill"
3. Aged 18 - 75 years, either sex
4. Sufficiently able to communicate with investigator, answer questions and fill in questionnaires
5. Reachability of patient for treatment and follow-up
6. Complience of patient
7. Undisturbed day-night rhythm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 patients and 10 matched healthy controls

Total final enrolment
20

Key exclusion criteria
1. Inability to give informed consent
2. Hospitalisation in a mental institution
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 internal medical illness, e.g., 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 8 weeks or discontinuation of psychopharmacological treatment within less than 2 weeks before beginning of the study
9. Recent interference with diurnal cycle
10. Current psychotherapeutic treatment specific for panic disorder and/or agoraphobia
11. Participation in other study within last month before beginning of the study or during the study

Date of first enrolment
01/03/2007

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Germany

Study participating centre
Clinic of Psychiatry and Psychotherapy
Berlin
Germany
10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

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Sponsor type
University/education

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) (ref: 01 GV 0612)

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	01/03/2011	21/08/2019	Yes	No