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Cortisol reactivity as a biomarker for depression

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/04/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

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
7554; G0801443

Study information

Scientific Title

Cortisol hyper-reactivity to stress - a putative biomarker for major depressive disorder

Study objectives
1. Cortisol hyper-reactivity is differentially present in individuals at high risk for depression
2. Cortisol hyper-reactivity is associated with negative cognitive biases proven to be associated with depression
3. Cortisol reactivity to stress is more strongly associated with risk factors for depression than are basal measures of cortisol

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 REC, 18/06/2009, ref: 09/H0308/69

Study design
Single-centre screening clinical laboratory study

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Screening

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
Topic: Mental Health Research Network; Subtopic: Depression, Stress-related and somatoform; Disease: Depression, Stress-related and somatoform disorders

Interventions
35% Carbon Dioxide Vital Capacity Inhalation Stress Test:
Participants insert the mouthpiece into their mouth. The three-way valve is set so they are breathing air. The experimenter asks the participant to breathe fully out, then take a breath as deep as they can, and hold it for 4 seconds, as a practice. The valve is changed so the CO2 tank is connected to the bag reservoir. The reservoir is filled. The valve is changed so the mouthpiece is attached to the CO2 in the reservoir. The participant breathes in and holds as with the practice.

Trier Social Stress Test:
The experimenter leads the participant to the experimental room at time 0, where they are introduced to two people (the 'committee'), a microphone and a video-camera. The experimenter tells the participant that they will have to deliver a speech for a job application to the committee, followed by another task, that will be detailed then. They are given instructions

by the committee, then prepare their speech until T +3 min. They are asked to deliver the speech. If they stop before 5 minutes, or their speech is not relevant, there are standard questions and prompts. Then they are asked to do the second task, where they must serially subtract 13 from 1022 as quickly and accurately as possible. After mistakes, they are asked return to 1022 and re-start. This lasts 5 minutes, then the task ends.

Each test happens once, and follow-up is for 60 minutes after start of test.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Salivary cortisol area under the curve in the time period after intervention, collected 20 minutes before and immediately before, and 20, 30, 40 and 60 minutes after, the onset of each stress test.

Secondary outcome measures
1. Performance on affective go:no go, measured at rest (before first stress test) and 30 minutes after the start of each stress test
2. Ratio of negative to positive words correctly recalled, measured at rest (before first stress test) and 25 minutes after the start of each stress test
3. Which stress test leads to largest rise in cortisol?

Overall study start date
13/04/2010

Completion date
31/01/2012

Eligibility

Key inclusion criteria
1. Aged 16 - 21 years old
2. Male and female
3. Recruited from Roots study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 228

Key exclusion criteria
1. Take regular steroid medication (oral or inhaled) or take hormonal contraceptives containing oestrogens (combined pill, injection, implant or patch)
2. Hypertension requiring regular treatment
3. Systolic blood pressure above 140 mmHg or resting pulse over 100 mmHg at the start of the study
4. Current respiratory disease, e.g., asthma
5. A personal or family history (parent or sibling) of panic disorder
6. Significant claustrophobia
7. Smoke daily; no smoking on day of assessment
8. Migraine within the last year
9. Current heart disease
10. Females will be excluded if they are or think they might be pregnant, are lactating, or their menstrual cycle has not returned to being regular after pregnancy
11. At least one biological grandparent known to be non-white European
12. At least one of the following psychiatric disorders at time of interview: anxiety disorder, OCD, oppositional defiant disorder, PTSD, conduct disorder, bipolar disorder
13. Alcohol or illicit drug use on the day of or the day before research assessment
14. Caffeine use since breakfast on the day of research assessment
15. Consume large amounts of caffeinated drinks on a regular basis (greater than six cups of coffee per day or drinks containing methylxanthines such as Pepsi or red bull)
16. Current severe cold or flu
17. Vigorous exercise for 2 hours before testing

Additional group-specific criteria:
18. Never-depressed participants:
18.1. No lifetime history of major depressive disorder
18.2. No lifetime history of at least one of the following psychiatric disorders: anxiety disorder, OCD, oppositional defiant disorder, PTSD, conduct disorder, bipolar disorder, ADHD
19. Recovered-depressed:
19.1. At least one past episode of major depressive disorder
19.2. At least 8 weeks of having fewer than two depressive symptoms since last episode
19.3. Not currently taking antidepressants
19.4. No lifetime history of ADHD, autism, conduct disorder with onset before age 11

Date of first enrolment
13/04/2010

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Developmental Psychiatry Section
Cambridge
United Kingdom
CB2 8AH

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust (UK)

Sponsor details
Cambridge Road
Fulbourn
Cambridge
England
United Kingdom
CB21 5EF
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natercia.godinho@cpft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cpft.nhs.uk/

ROR
https://ror.org/040ch0e11

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0801443)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

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