

Cortisol reactivity as a biomarker for depression

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Single-centre screening clinical laboratory study

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s)

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?

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Developmental Psychiatry Section

Cambridge

United Kingdom

CB2 8AH

Sponsor information

Organisation

Cambridgeshire and Peterborough NHS Foundation Trust (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration