Memory formation under stress in humans: Iinvestigation into the importance of hormone receptors.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19893

Source
NTR

Brief title
Mem&MR

Health condition

Stress
Cortisol
emotional memory
spatial memory

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: NWO funding. investigator-driven research.

Intervention

Outcome measures

Primary outcome

At the behavioural level, the main study parameter in the spatial memory task is accuracy (i.e. how well subjects remember the right location for a given object learned earlier) and the strategy used (i.e., automatic stimulus response association or elaborate spatial map strategy). For fear acquisition we assess how fast and accurate subjects learn the relationship between specific stimuli and threat using skin conductance responses. At the brain system level, we seek to investigate whether neural response patterns obtained by fMRI can reveal the neural mechanism by which MR activation is causing stress induced changes in spatial memory and fear learning.

Secondary outcome

1. Baseline levels of salivary cortisol (the first 3 saliva samples are used to compute an individual baseline cortisol level per participant);

2. Changes in blood pressure and heart rate;

3. Changes in resting state connectivity due to stress and administration of an MR blocker;

4. Personality and life events questionnaires:

A. State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983);

B. Life Threatening Events (LTE) (Brugha & Cragg, 1990);

C. Shortened Temperament and Character Inventory (TCI; Cloninger, 1994);

D. Trier Inventory of Chronic Stress (Trier Inventory of Chronic Stress, TICS-LE. Unpublished English Version);

E. Herinneringen aan de opvoeding, short form (EMBU-s; Arrindell et al., 1999), a questionnaire on early life parental care.

5. Mood state questionnaires:

A. Positive Affect Negative Affect (PANAS) (Watson et al., 1988);

B. State-Trait Anxiety Inventory (STAI) (Spielberger et al., 1970) to assess state anxiety;

C. Mood rating scale (Bond & Lader, 1974), extended with 8 items to assess evaluation of the study situation.

Study description

Background summary

N/A

Study objective

N/A

Study design

1 appointment for a medical screening, 2 appointments for the actual testing (3.5h and 1h, both in the afternoon on subsequent days).

Intervention

Half of the subjects will undergo a slightly modified version of the Socially Evaluated Cold Pressure Task (SECPT; Schwabe, Haddad, & Schachinger, 2008) to induce stress. The other half will undergo a control condition meant to cause no stress. Furthermore, half the subjects of the stress- and the non stress-group will receive a single dose Spironolacton (400mg tablet) before undergoing fMRI; the other participants will receive placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male, healthy volunteers;

2. Age 18 - 35 years;

3. Normal or corrected-to-normal vision;

4. Normal uncorrected hearing;

5. Body mass index between 18.5 and 30;

6. Willingness and ability to give written informed consent and willingness and ability to understand the nature and content, to participate and to comply with the study requirements.

Exclusion criteria

1. Anuria;

2. Acute or history of renal insufficiency / impairment of renal excretory function (or creatinine levels > 1.1 mg/dl at screening);

3. Hyperkalemia (or potassium levels of > 5.0 mEq/L at screening);

4. History of psychiatric treatment /current psychiatric treatment;

5. History of neurological treatment /current neurological treatment;

6. History of endocrine treatment /current endocrine treatment;

7. History of autonomic failure (e.g., vasovagal reflex syncope);

8. History of psychotropic medication (e.g. antidepressants);

9. History of hepatic impairments;

10. History of cardiovascular diseases;

11. Hypotension (< 90 / 60 mmHG);

12. Bradycardia / Tachycardia (heart rate < 50 or > 100 at rest);

13. Use of any medication on a regular basis;

14. Metal objects in or around the body;

15. Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel);

16. Claustrophobia;

17. Use of recreational drugs weekly or more often;

18. Smoking of more than 5 cigarettes per day;

19. Average use of more than 3 alcoholic beverages daily and self-reported inability or un-ease to cease drinking alcohol for 24 hours prior to testing;

20. Coffeine consumption 24 hours before testing;

21. Professional sports or participation in competitions (as Spironolacton can lead to a positive doping test).

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2012
Enrollment:	96
Type:	Actual

Ethics review

Positive opinion

Date:	29-08-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35544
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3444
NTR-old	NTR3595
CCMO	NL37819.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35544

Study results

Summary results
N/A