Acute effects of 40 mg cortisol on emotion and cognition.

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To investigate acute effects of a single 40 mg dose hydrocortisone, compared with placebo, on stress and various aspects of attention and other cognitive processing of emotionally relevant stimuli in healthy anxious young females. The main question...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON44224

Source
ToetsingOnline

Brief title
Cortisol, Emotion and Cognition

Condition

- Anxiety disorders and symptoms

Synonym
biased cognition, selective attention

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: VIDI grant Dr. P. Putman

Intervention

Keyword: cognitive performance, cortisol, emotion, stress

Outcome measures

Primary outcome

Performance (measured response times and accuracy scores) on various computerized tasks that measure attentional processing of emotional stimuli and executive cognitive performance. Also, self-reported cognitive interference during cognitive performance will be assessed. Finally, we will Assess resting-state EEG, salivary cortisol concentration, several self-reported psychological trait questionnaires and self-reported state anxiety and state attentional control.

Secondary outcome

As a secondary aim, we will examine whether the effects of hydrocortisone on cognition are moderated by frontal EEG theta/beta ratio (or other trait characteristics such as trait attentional control as assessed by the ACS). In order to test this hypotheses, mixed ANCOVAs will be performed with the same between and within-subjects factors, as described in section 10.1, and theta/beta ratio (or ACS) as covariate (s). If applicable, follow-up simple slope analyses will be performed to reveal the nature of significant moderational interactions.
The negative relationship between theta/beta ratio and attentional control will be tested with Pearson's correlations and partial correlations, controlling for trait anxiety.

Study description

Background summary

Previous evidence suggests that large single doses of exogenous cortisol (hydrocortisone) have acute effects on cognitive processing of emotional stimuli. However, such effects of hydrocortisone on cognitive performance under acute stress have never been tested even though this would be of considerable fundamental and eventually possibly practical importance. This should be investigated by assessing cognitive performance under stress and the influence of hydrocortisone administration hereon.

Study objective

To investigate acute effects of a single 40 mg dose hydrocortisone, compared with placebo, on stress and various aspects of attention and other cognitive processing of emotionally relevant stimuli in healthy anxious young females. The main question is whether hydrocortisone counters the negative effects of stress on executive cognitive performance. This may provide new information about the role of cortisol in processes of emotion regulation under stress that are important in affective psychopathology. This is a fundamental scientific purpose. In particular, the proposed project will contribute to a better understanding of the results obtained previously by the CME LUMC projects reviewed P06.189 and P08.007. Please note that this is not a study of medicinal properties, pharmacodynamics or *kinetics for a medicinal pharmacon. Rather, this study investigates non-medicinal effects which are of fundamental interest without direct medicinal relevance by a pharmacon that happens to be used for unrelated medicinal purposes. As such this is not a *geneesmiddelenonderzoek* as referred to in the WMO.

Study design

A double-blind, placebo-controlled between-subjects experiment.

Intervention

Participants will receive either a placebo or 40 mg of hydrocortisone as capsules for oral intake, in the afternoon after limited dietary restrictions (no intake of nutrients 1.5 hour prior to drug/placebo administration).

Study burden and risks

Tax risks and benefits of participating subjects: The main burden on the subjects is probably the time investment (about 3,5 hours) which is associated with study participation. Participants perform a task with positive or negative

pictures (e.g. mutilated bodies or erotic pictures) that might be arousing, that are commonly used for psychology experiments. A laboratory psychosocial challenge will induce stress but that is not uncommon for students who frequently undergo evaluation in the academic environment. Implementation of some low-demand computerized cognitive tasks can be experienced as tiresome or boring. A single administration of 40 mg of hydrocortisone does not lead to subjectively noticeable effects on physical or mental functioning and is harmless. Other than a relatively small monetary reward participation does not offer direct personal benefit to the participant.
The aim of this study is closely related to an earlier study conducted in Leiden University that have been previously approved by the Medical Ethics Committee of the Leiden University Medical Center (CME IDs P06.189, P04.077, P08.007, P11.195). All these studies employed the same study pharmacological manipulation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

good physical health
17female

Exclusion criteria

-use of prescription medication
-history of psychiatric, neurologic, or endocrine illness

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2017
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	hydrocortisone
Generic name:	hydrocortisone

Ethics review

Approved WMO Date:	19-09-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-10-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-003331-10-NL
CCMO	NL62072.058.17