

# Acute effects of 40 mg cortisol on mental functions II

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The closer examination of acute effects of a single administration cortisol. compared to placebo, on different aspects of attention and other cognitive processing of emotionally relevant stimuli in healthy young men. The central question is what...

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

## Summary

### ID

NL-OMON35558

### Source

ToetsingOnline

### Brief title

cortisol and mental functions II

### 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:** NWO vernieuwingsimpuls (veni) op naam van Dr. P. Putman

## Intervention

**Keyword:** attention, cortisol, emotion, HPA

## Outcome measures

### Primary outcome

Patterns of performance (measured as response times and accuracy) on different computer tests measuring emotional cognitive behavior and non-invasive psychophysiological measures.

### Secondary outcome

N/A

## Study description

### Background summary

Rationale: Earlier reports in the scientific literature and other studies of the present researcher suggest that exogenous cortisol can have acute effects on the (attentive) cognitive processing of threat-related stimuli. Results obtained with several different cognitive and psychophysiological methods do however not always overlap in detail. A factor that seems to be of relevance is if the emotional stimuli are relevant or irrelevant to task performance. This needs to be specified and tested by means of systematic manipulation of this factor.

### Study objective

The closer examination of acute effects of a single administration cortisol, compared to placebo, on different aspects of attention and other cognitive processing of emotionally relevant stimuli in healthy young men. The central question is what role task relevance of the emotional stimuli plays. This can provide new information about the role that cortisol plays in processes of emotion regulation which are important in affective disorders. This mainly serves a fundamental scientific purpose.

### Study design

A doubleblind, placebo-controlled cross over experiment to test acute effects of 40 mg hydrocortisone on performance on different cognitive computertests.

## **Intervention**

Participants will receive placebo and 40 mg hydrocortisone once.

## **Study burden and risks**

Burden, risks and benefits for participants: De main bnurden for the aprticipan probably lies in the time investment (approximately 6 hours). Performance of several cognitively mildly taxing computertasks can be experienc4ed as boring or tiresome. Single adminstration of 40 mg hydrocortisone does not lead to subjectively noticeable effects on physical of mental functioning and is safe and non-hazardous. Other than a relatively small monetary incentive (50 euro's) there is no direct benefit for participation to the study.

## **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

17 < age < 31 years

male

### 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):	19-04-2012
Enrollment:	24
Type:	Actual

## Ethics review

Approved WMO

Date: 03-02-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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
CCMO	NL38018.058.11