# Timing, cortisol, and brain function: Probing the time-dependent effects of cortisol on the neural correlates of cognitive processes

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32936

**Source**
ToetsingOnline

**Brief title**
Timing, cortisol, and brain function

### Condition

- Other condition

**Synonym**
/

**Health condition**

geen aandoening

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** NWO: Toptalent beurs

## Intervention

**Keyword:** cortisol, funtional MRI, memory, time-dependent effects

## Outcome measures

### Primary outcome

The main variable of interest is the brain activity measured during the computer tasks, in combination with the cortisol levels assessed from the participant*s saliva. To determine this level participants will be asked several times during the experiment to chew on a cotton cloth in order to obtain saliva. By comparing the data between groups we will be able to elucidate the effects of cortisol on the brain and to determine the time- and region-dependency.

### Secondary outcome

Besides brain activity we will measure several physiological and psychological measures during fMRI scanning; heart beat, blood pressure, skin conductance, pupil size, eye movement, reaction times, and the mood of the participant. These variables, in combination with personality traits assessed by several questionnaires, can be entered in the analysis of the cortisol effects as well.

# Study description

### Background summary

Stressful events have a privileged position in memory. The effects of so-called stress hormones on the brain are held responsible for this. Cortisol is such a stress hormone that is known to bind to specific receptors localized in the brain, but which effect on brain activity and function are still rather unknown. Animal studies have shown that cortisol has potentially contradicting rapid direct, and slow genomic effects on the brain.

### Study objective

With this research we would like to assess the effects of cortisol on the brain, and determine whether these effects are region- and time-specific. Our main interest is focused on the effects of cortisol on the regions involved in memory formation and related higher cognitive functions, as working memory, attention and emotional processing; the medial temporal lobe (MTL) and the prefrontal cortex (PFC).

### Study design

All participants will be invited to the lab for two subsequent afternoons. The first afternoon they will receive two tablets (doubleblind) at different time points, of which maximally one contains 10 mg hydrocortisone and the other placebo (see *Intervention*). By elevating the level of cortisol either 240 minutes or 30 minutes prior to a functional MRI session, we will be able to both assess the slow genomic and rapid direct effects of cortisol on the brain. During the functional MRI session participants are asked to conduct several computer tasks, which activate the regions of interest; the MTL and PFC. These tasks assess long term memory, working memory, emotional processing, attention, and rest. The second afternoon participants are asked to return to the center, and have to conduct a short memory test for some of the information studied in the scanner.

### Intervention

Participants will by randomly assigned to one of the three groups. During the first afternoon, each group will receive two tablets, at different time points prior to the scanning session:
- group 1: 240 min prior to scanning 10 mg hydrocortisone
30 min prior to scanning placebo
- group 2: 240 min prior to scanning placebo
30 min prior to scanning 10 mg hydrocortisone
- group 3: 240 min prior to scanning placebo
30 min prior to scanning placebo

### Study burden and risks

Both the burden and risk of participation are not considered to be high. The

research requires a total time-investment of 7 hours, divided over two subsequent afternoons. All procedures followed are without any danger and we do not expect any side effects from the proposed administration of such a low dose of hydrocortisone that is administered only once.

## 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

• Healthy male volunteers between 18 and 45 years of age
• Predominant right-handedness
• Body mass index between 18.5 and 30

### Exclusion criteria

• Abnormal (uncorrected) vision
• Average use of more than 3 alcoholic beverages daily and a self-reported inability or unease to cease drinking alcohol for 24 hours prior to testing
• Use of psychotropic medication
• Average use or recreational drugs weekly or more
• Habitual smoking, i.e. more than a package of cigarettes per week and a self-reported inability or unease to cease smoking for 24 hours prior to testing
• Use of recreational drugs over a period of 72 hours prior to each test session, and use of alcohol within the last 24 hours before each measurement
• Regular use of corticosteroids
• Metal objects in or around the body (braces, pacemaker, metal fragments, hearing devices)
• History of psychiatric treatment or current psychiatric treatment
• History of neurological treatment or current neurological treatment
• History of endocrine treatment or current endocrine treatment
• History of autonomic failure (e.g., vasovagal reflex syncope)
• Current parodontitis
• Claustrophobia
• Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel)
• Active peptic or duodenal ulcers
• Active inflammatory disease

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 10-04-2009 |
| Enrollment: | 72 |
| Type: | Actual |

### Medical products/devices used

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| Registration: | No |

## Ethics review

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| Approved WMO Date: | 06-04-2009 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL26345.091.08 |