Conditioning cortisol

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20814

Source
Nationaal Trial Register

Brief title
CONCO

Health condition

This study will be conducted in healthy volunteers.

Sponsors and support

Primary sponsor: Leiden University
Health, Medical, and Neuropsychology Unit
Institute of Psychology
Faculty of Social and Behavioural Sciences
Source(s) of monetary or material Support: Governement funding

Intervention

Outcome measures

Primary outcome

The main study parameter is the AUCg of endogenous cortisol during rest in the evocation phase.

Secondary outcome

Secondary study parameters are the AUCg of endogenous cortisol during exposure to a short-term psychosocial stress task. Alpha-amylase and self-reported well-being during rest and during exposure to a short-term psychosocial stress task in the evocation phase are additional secondary parameters.

Study description

Background summary

Background:

Preliminary evidence suggests that it might be possible to condition endogenous cortisol, with subsequent psychophysiological effects. In a pilot study with ten participants, promising indications were found for conditioned effects on endogenous cortisol levels and other psychophysiological outcomes. When more systematic research in a larger sample would support these findings, the ability to condition cortisol could offer new therapeutic possibilities.

The aim of this study is to investigate the effects of conditioning with hydrocortisone on endogenous cortisol. Effects of conditioning on endogenous cortisol in response to a short-term psychosocial stress task and other psychophysiological outcomes will also be explored.

Study design:

In line with previous conditioning studies as well as the previous pilot study in ten participants with an analogous design conducted by the research group, a randomized placebo-controlled conditioning paradigm consisting of 2 phases will be applied. In the acquisition phase, consisting of 3 sessions on 3 consecutive days, an unconditioned stimulus (experimental condition: hydrocortisone pill; control condition: placebo pill) is paired with a conditioned stimulus (novel tasting beverage). In the evocation phase, also consisting of 3 sessions on 3 consecutive days a week after the acquisition phase, all participants will be administered a placebo pill paired with the same beverage as in the acquisition phase. Cortisol, alpha-amylase, and self-reported well-being will be measured at several time points during the 6 acquisition and evocation sessions. During each session, participants will also be asked to perform some cognitive tasks and during the last session participants will be exposed to a short-term psychosocial stress task.

Study objective

Conditioning with hydrocortisone will result in
altered endogenous cortisol during rest in the evocation phase.

Study design

During the sessions, cortisol, alpha-amylase and self-reported well-being are measured at several time points

Intervention

In the experimental group, cortisol is elevated exogenously on three consecutive days by administration of 100 mg hydrocortisone. In the control group, a placebo is administered at the same time points.

Contacts

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Eligibility criteria

Inclusion criteria

healthy, female, premenopausal, 18-30 years of age

Exclusion criteria

Somatic and/or psychiatric diseases, symptoms of infection, use of medication (including oral contraceptives), recent stressful life events

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2014
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-06-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47397
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4409
NTR-old	NTR4651
CCMO	NL47105.058.14
OMON	NL-OMON47397

Study results