Conditioning cortisol and its psychophysiological effects

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To investigate the effects of conditioning with hydrocortisone on endogenous cortisol. Effects of conditioning on endogenous cortisol in response to a validated short-term psychosocial stress task and other psychophysiological outcomes will also be...

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

Summary

ID

NL-OMON47397

Source
ToetsingOnline

Brief title
Conditioning cortisol

Condition

- Other condition

Synonym
Not applicable

Health condition

Het onderzoek wordt bij gezonde proefpersonen uitgevoerd. Uitkomsten uit deze lijn van onderzoek bieden nieuwe handvatten voor verklaringsmodellen en therapeutische interventies voor aandoeningen waarbij een verandering in de functie van de HPA-as optreedt.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W,European Research Council Consolidator Grant

Intervention

Keyword: conditioning, cortisol, psychophysiological parameters

Outcome measures

Primary outcome

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

Secondary outcome

Secondary study parameters are the AUCg of cortisol during exposure to a validated short-term psychosocial stress task, as well as the autonomic parameters alpha-amylase, heart rate, and skin conductance, and the psychological parameter self-reported well-being during the evocation phase. Additionally, to explore the possible influence of genotype on the effects of conditioning, the 5-HTTLPR genotype and other candidate genotypes will be assessed.

Study description

Background summary

Preliminary evidence suggests that it might be possible to condition endogenous cortisol, with subsequent psychophysiological effects. In a pilot study for the current study, medium to large effect sizes were found for conditioned effects on endogenous cortisol levels and other psychophysiological outcomes. When more systematic research in a sufficiently powered sample would support these findings, the ability to condition cortisol could offer new therapeutic

possibilities.

Study objective

To investigate the effects of conditioning with hydrocortisone on endogenous cortisol. Effects of conditioning on endogenous cortisol in response to a validated short-term psychosocial stress task and other psychophysiological outcomes will also be explored. Additionally, the possible influence of the 5-HTTLPR genotype and possible other genetic variants on the effects of conditioning will be explored.

Study design

In line with previous conditioning studies as well as the previously conducted pilot study 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 association between an unconditioned stimulus (experimental condition: hydrocortisone pill; control condition: placebo pill) and a conditioned stimulus (novel tasting beverage) will be established. 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. In the acquisition phase, baseline measurements of cortisol, alpha-amylase, and self-reported well-being will be taken in each session. In the evocation phase, cortisol, alpha-amylase, and self-reported well-being will be measured at several time points, and heart rate and skin conductance will be monitored continuously. In each evocation session, participants will also be asked to perform some cognitive filler tasks and during the last session participants will be exposed to a validated short-term psychosocial stress task. Successful conditioning would be shown by a conditioned response (change in endogenous cortisol) after exposure to the conditioned stimulus (the beverage paired with a placebo pill) in the evocation phase. Additionally, the study will explore whether conditioning of cortisol has effects on other psychophysiological outcomes such as autonomic functioning and well-being.

Intervention

In the experimental group, cortisol is elevated exogenously on three consecutive days by administration of 100 mg hydrocortisone.

Study burden and risks

Participants need to invest 1,5 hours for the first session. The 3 acquisition sessions will take approximately 15 to 20 minutes and each of the evocation sessions lasts on average 2,5 hours. This results in a total time investment of ca. 10 hours across three weeks. During the acquisition phase, 100 mg of

hydrocortisone will be administered to half of the participants on three consecutive days. Given the safety outcomes of our pilot study, the short half-life of hydrocortisone (8-12 hours), and the administration of only 3 doses, no adverse side effects are expected (although they will naturally be monitored), especially as this study is conducted in healthy individuals. Also, all participants will be asked to perform some cognitive filler tasks and will be exposed to a validated short-term psychosocial stress task during the last session. Subjects will receive a reimbursement of ¤150,- for participation in this 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

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 major stressful life events

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2014
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	26-02-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-03-2017
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-06-2018
Application type:	Amendment
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

ID: 20814
Source: NTR
Title:

In other registers

Register	ID
Other	Nederlands Trial Register (NTR) nummer TC=4651
CCMO	NL47105.058.14
OMON	NL-OMON20814

Study results

Date completed:	20-07-2018
Actual enrolment:	48