Pilot study on conditioning cortisol levels and its psychophysiological effects

Published: 23-08-2012
Last updated: 26-04-2024

To test the feasibility of a conditioning paradigm aimed at influencing endogenous cortisol levels and provide data for power calculations for the main study on conditioning of endogenous cortisol and its psychophysiological effects.

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

Summary

ID

NL-OMON37492

Source
ToetsingOnline

Brief title
Pilot study: Conditioning cortisol

Condition

- Other condition

Synonym
Niet van toepassing

Health condition

Op dit moment wordt het onderzoek bij gezonde proefpersonen uitgevoerd. Uitkomsten uit deze lijn van onderzoek bieden in de toekomst mogelijk nieuwe handvatten voor verklaringsmodellen en therapeutische interventies voor aandoeningen waarbij een verstoring in de functie van de HPA-as optreedt.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: conditioning, cortisol, psychophysiological parameters

Outcome measures

Primary outcome

The main study parameters of the pilot study are the feasibility of the design (e.g., most useful assessment points for the psychophysiological assessments, safety, drop-out). Variance of endogenous cortisol levels at the evocation phase as well as correlations between cortisol levels at the evocation phase and at baseline in the experimental group will also be assessed, in order to enable a founded power analysis for the main study. In the main study, the main study parameters will be endogenous cortisol levels and psychophysiological parameters (e.g., in response to cognitive and psychosocial tasks) at the evocation phase.

Secondary outcome

Not applicable

Study description

Background summary

There is preliminary evidence that endogenous cortisol levels might be subject to manipulation by conditioning, which may have psychophysiological effects. The ability to condition cortisol can offer new therapeutic possibilities. However, more systematic research is needed to support these findings.

Study objective

To test the feasibility of a conditioning paradigm aimed at influencing endogenous cortisol levels and provide data for power calculations for the main study on conditioning of endogenous cortisol and its psychophysiological effects.

Study design

A randomized placebo-controlled conditioning paradigm consisting of 2 phases will be tested.
In the acquisition phase, consisting of 3 sessions on 3 consecutive days, an association between an unconditioned stimulus (cortisol or 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. Cortisol, alpha-amylase and self-reported wellbeing will be measured at several time points and heart rate and skin conductance will be monitored continuously during the 6 acquisition and evocation sessions. At each of these sessions, participants will also be asked to complete some cognitive and psychosocial tasks. Successful conditioning would be shown (in the main study) by a conditioned response (change in endogenous cortisol level) after exposure to the conditioned stimulus (the beverage paired with a placebo pill) alone. Additionally, the main study will investigate whether conditioned cortisol levels have psychophysiological effects.

Intervention

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

Study burden and risks

Participants need to invest 1 hour for the first session and on average 2,5 hours on each following session across 2 weeks. During the acquisition phase, 100 mg of hydrocortisone will be administered to half of the participants on three consecutive days. Given the short half life of hydrocortisone (8-12 hours) and the fact that only 3 doses are administered, 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 and psychosocial tasks.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6524 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6524 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy, female, premenopausal, 18 - 45 years of age

Exclusion criteria

Severe psychiatric and/or somatic diseases, symptoms of infection, use of medication (including oral contraceptives), recent stressful life event

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):	01-07-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-08-2012
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	NL40509.091.12