Conditioning of the neuroendocrine system: learned oxytocin responses

Published: 22-04-2015
Last updated: 15-05-2024

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

Summary

ID

NL-OMON42539

Source
ToetsingOnline

Brief title
Learned oxytocin responses

Condition

- Other condition

Synonym
not applicable

Health condition

Het onderzoek wordt bij gezonde personen uitgevoerd. Uitkomsten uit deze lijn van onderzoek bieden nieuwe handvaten voor verklaringsmodellen en therapeutische interventies voor aandoeningen waarbij een verandering in de functie van het endocriene systeem optreedt.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: ERC Consolidator Grant

Intervention

Keyword: conditioning, neuroendocrine system, oxytocin, placebo

Outcome measures

Primary outcome

The main study parameter is salivary oxytocin level during evocation in the experimental group compared to the placebo group. Oxytocin will be measured four times during the first two evocation sessions (once before and in 5, 20 and 30 after the drug or placebo administration) and twice during the third evocation day.

Secondary outcome

Additional study parameters assessed at baseline and at the evocation phase are: salivary cortisol, pain sensitivity and during the third evocation day only, resting state and task-related (emotional faces, infant crying, and pain stimulation) brain activity, pain sensitivity levels and physiological data using the nociceptive level index during thermal pain stimulation.
Additionally, to explore the possible influence of genotype on the effects of conditioning, the 5-HTTLPR genotype and other candidate genotypes will be assessed in saliva.

Study description

Background summary

Preliminary evidence suggests that endogenous hormone secretion, such as cortisol or insulin, might be behaviourally conditionable in humans. Whether other neuroendocrine hormones such as oxytocin can be conditioned as well is currently unclear and no studies focused yet on possible neural mechanisms of conditioning.

Study objective

The primary objective is to investigate the effect of conditioning with oxytocin on endogenous oxytocin release. Secondary, we will investigate the effect of oxytocin conditioning on cortisol and on brain activity, both in resting state and in response to tasks relevant to oxytocin release.

Study design

A previously validated two-phase randomized placebo-controlled conditioning paradigm will be applied. After a screening session, participants will be randomly allocated to one of three groups: 1) an experimental group, 2) a placebo group, or 3) a drug-control group. In the first phase, the acquisition phase, a distinctive odor (conditioned stimulus, CS) will be associated with the administration of either exogenous oxytocin (unconditioned stimulus, US; experimental and drug-control groups) or placebo (placebo group) on three consecutive days. The second phase, the evocation phase, will start 4 days after the last acquisition day. Participants in the experimental and placebo groups will be given a placebo in combination with the CS during three consecutive days, whereas the drug-control group receives oxytocin without the CS. During the last evocation day, a functional Magnetic Resonance Imaging (fMRI) brain scan will be conducted in all groups.

Intervention

In the experimental group, participants will receive a 24 IU dose of oxytocin via a nasal spray during the acquisition phase and an identically looking placebo nasal spray during the evocation phase. In the placebo group, participants will receive a placebo in both phases. In the drug-control group, 24 IU oxytocin will be administered in both phases.

Study burden and risks

Risks associated with the study procedures are minimal. Several studies have been conducted in humans with repeated doses up to 80 IU of oxytocin without reporting adverse side effects. There are no known risks associated with non-invasive fMRI acquisition and participants will be screened for claustrophobia. The standardized pain application device (Pathway, Medoc) has built-in safeguards. Participants can stop the study at any time for any reason. The burden of study participation is considered moderate, involving an

approximate total time investment of 6 hours and 20 minutes. Studying the effects of oxytocin conditioning will shed more light on the mechanisms of conditioning endocrine parameters and on various physiological and psychological functions.

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, 18-35 years old, right-handed, using oral contraceptives

Exclusion criteria

Somatic and/or psychiatric conditions, (intendend) pregnancy or breast-feeding, heavy use of (illegal) drugs including cannabis and habits of heavy drinking, known sensitivity or hypervigilance to one of the ingredients of the oxytocin or the odor used in this experiment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2016
Enrollment:	99
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-09-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-10-2015
Application type:	Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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: 20692
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52683.058.15
OMON	NL-OMON20692