An investigation of the effects of oxytocin on communication

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To identify the brain and behavioral mechanisms via which oxytocin modulates communicative behavior.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35456

Source
ToetsingOnline

Brief title
The effects of oxytocin on communication

Condition

- Other condition

Synonym
n.v.t.

Health condition

sociaal gedrag

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: communication, oxytocin

Outcome measures

Primary outcome

- Behavioral performance and brain activity on computerized tasks

Secondary outcome

- Subjective measurements on self-report questionnaires.

- Functional connectivity of the human brain by examining intrinsic BOLD

fluctuations.

Study description

Background summary

Many studies showed that oxytocin, a hormone and a neurotransmitter, plays an important role in the formation of social, affiliative behavior.
Intranasal administration of oxytocin in humans has been reported to enhance trust, empathy and social engagement. However, knowledge on how oxytocin affects human brain and behavior during communication, which is our most prevalent social behavior, is scarce. The main objective of our research is therefore to provide insights into how oxytocin modulates communicative behavior.

Study objective

To identify the brain and behavioral mechanisms via which oxytocin modulates communicative behavior.

Study design

Participants will be tested in a randomized, double-blind, placebo controlled, between-group design. Participants will receive either oxytocin or a similar placebo dose and perform computerized tasks. After the tasks, participants will complete several self-report questionnaires.

Intervention

One group of participants will self-administer 48 IU of Syntocinon - the synthetic analogue of oxytocin - by an intranasal spray. Another group will self-administer a similar dose of placebo.

Study burden and risks

The low dose of oxytocin can be administered safely to humans without any relevant risk of serious adverse events. On both the day prior to the test session and on the day of the test session itself participants will adhere to some simple restrictions with respect to medication, alcohol and drug intake. In the morning of the test day, participants will refrain from smoking and consuming stimulant-containing drinks. The risk associated with participation can be considered negligible and the burden can be considered minimal. No adverse events are expected and side effects of the treatment are very unlikely.

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 35 years of age
Predominant right-handedness

Exclusion criteria

- 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 heart-related disease
- Regular use of corticosteroids
- Metal objects in or around the body (braces, pacemaker, metal fragments, hearing devices).
- Body Mass Index < 18.5 or > 25
- Claustrophobia
- History of epilepsy

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: Pending

Start date (anticipated):	01-12-2011
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	15-02-2012
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	NL37419.091.11