The effects of oxytocin on implicit empathic behavior

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To study whether the administration of oxytocin leads to stronger empathic responses on 3 different empathy-related tasks compared to a placebo.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON36038

Source
ToetsingOnline

Brief title
Oxytocin and empathy

Condition

- Cognitive and attention disorders and disturbances

Synonym
emotional processing, empathy

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: emotion, empathy, oxytocin

Outcome measures

Primary outcome

- Electromyographic (EMG) responses of the zygomatic major and corrugator supercilii to presented happy and angry faces.

- Attentional bias to happy and anxious faces over neutral faces

- Amount of distraction by emotional pictures compared to neutral pictures during a working memory task

Secondary outcome

The effect of oxytocin administration will be compared between subjects that score high or low on questionnaires measuring, anxiety, depression, empathy and autistic traits

Study description

Background summary

Empathy is a human emotion related to understanding and feeling the emotions of others. Lately, there has been increasing interest in the neurobiological backgrounds of empathy. The hormone oxytocin (OT) seems to play an important role in empathy. Administration of the hormone to humans is related to better emotion recognition and an increase in positive social interactions. Furthermore, genetic variants of the OT receptor genes are related to autism, a disorder characterized by problems in empathic abilities. However, little is known about the causal relation between oxytocine and empathic behavior in healthy humans. In this double blind cross-over study we will therefore investigate the effects of 24 IU intranasal oxytocin administration on implicit empathic behaviors in healthy male volunteers. More knowledge on the relation between OT and empathy may stimulate research in disorders characterized by changes in OT or empathy, like autism and social anxiety.

Study objective

To study whether the administration of oxytocin leads to stronger empathic

responses on 3 different empathy-related tasks compared to a placebo.

Study design

A placebo-controlled double-blind crossover design in which 20 male participants once receive 24 IU of oxytocin via a nasal spray and once a placebo nasal spray after which they perform 3 different empathy related tasks. The sprays are given on 2 separate days.

Intervention

24 IU oxytocine nasal spray versus placebo nasal spray

Study burden and risks

The associated risk and burden by the intranasal oxytocin spray are minimal and the participants are paid for the time they invest. The mimicry task will give little burden when the electrodes are stuck to the face. The emotional faces in the mimicry and attentional bias task are designed to elicit emotional reactions, but are not strongly arousing. The pictures in the working memory task may elicit more arousal, but will only be presented briefly (1.5 sec). The students (mostly in the social sciences) that will participate will learn about experimental psychological research and will get a summary of the results of 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

Male
Age 18 - 35
Healthy (physical and mental)

Exclusion criteria

Major physical illness such as heart problems, high blood pressure, diabetis, epilepsy, liver disease, or any other serious medical condition.
Current or past (< 5 years) psychiatric disorders, assessed by selfreport.
Medication use that can interfere with the study.
Use of more than 3 glasses of alcohol per day.
Use of more than 10 cigarettes per day.
Use of hard drugs.
Common use of soft drugs (e.g. cannabis) - at least once per week in the last 3 months.

Study design

Design

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

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon
Generic name:	oxytocin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-04-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-07-2011
Application type:	First submission
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: 22193
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-001708-37-NL
CCMO	NL36378.058.11
Other	wordt nog toegekend
OMON	NL-OMON22193