Effects of oxytocin on approach behavior and social action control

Published: 16-03-2010
Last updated: 02-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Environmental issues
Study type	Interventional

Summary

ID

NL-OMON35112

Source
ToetsingOnline

Brief title
OXT and social behavior

Condition

- Environmental issues

Synonym
n/a

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO (VENI)

Intervention

Keyword: action control, approach behavior, oxytocin, social cognition

Outcome measures

Primary outcome

Main outcome-measures consist of the results of the test battery measurements

including trait questionnaires and repeated measurements (state measurements)

of subjective effects assessed using the Bond and Lader Mood Rating Scale.

Secondary outcome

n/a

Study description

Background summary

Appropriate social behavior is vital for human health and well-being, although the neurobiological mechanisms which mediate social behavior remain poorly understood. Oxytocin (OXT) is a neurohypophysial nonapeptide which is synthesized in the supra-optic (SON) and the parvoventricular (PVN) nuclei of the hypothalamus and its release is under serotonergic control (Gimpl & Fahrenholz 2001). Oxytocin has, next to its peripheral effects (i.e. induction of parturition and lactation), received attention for its role in social behavior and has been suggested to induce prosocial behavior in animals as well as in humans, without side effects (Campbell 2007; Domes, Heinrichs et al. 2009; Kosfeld et al., 2005; Young 2002; Zak, Stanton et al. 2007). As these studies have used a wide variety of tests, from trust games to emotion detection, the concept of genuine, standardized approach behavior remains rather vague. The current study aims at employing two paradigms that provide more concrete manifestations of affiliative behavior and social motivation which, as widely suggested, ought to be boosted by oxytocin (Depue & Morrone-Strupinsky, 2005).
Furthermore, the effect of oxytocin on action control in a joint task setting shall be examined. As Sebanz et al. (2003, 2005) have shown, representing the other*s action in a joint setting affects one*s own performance in a spatial (in-) compatibility task (Social Simon Task). During co-acting, low-level processing of irrelevant cues occurs automatically and leads to longer RTs to incompatible stimuli. The social context additionally modulates this effect as

the interference is enlarged in the joint setting (Sebanz et al., 2005).
The Ultimatum Game has been shown to be responsive to the pro-social effects of oxytocin as trusting other people is a precondition of affiliation (Heinrichs et al., 2009). The administration of oxytocin results in greater risk taking in social situations (Kosfeld et al., 2005), thus promoting approach behavior.
Conversely, several psychiatric disorders are associated with disturbances in social motivation and social behavior. Apart from social anxiety, social deficits also occur in patients with Autism Spectrum Disorders (ASD), Obsessive-Compulsive Disorder (OCD), Borderline Personality Disorder (BPD) or Depression.
The current study aims to address abovementioned issues regarding oxytocin effects on approach behavior and action control in healthy volunteers. Results of this study will be used to optimize the design of a future study to assess the effects of oxytocin in patients with depression, which will be separately communicated to the local ethics committee at that time.

Study objective

The main objective of the present protocol is to investigate to what extent oxytocin modulates specific aspects of approach behavior and action control in healthy volunteers
Results from this study shall give rise to designing a future study on the effects of oxytocin in patients diagnosed with depression.

Study design

This proposal consists of a double-blind, placebo-controlled, two-way cross-over experiment. 16 volunteers will be randomly assigned to one of two treatment sequences. Each volunteer will receive a nasal spray containing oxytocin or placebo with an interval of 14 days between each treatment and subjects will perform a test battery.

Intervention

24 intranasal units (IU) of oxytocin, administered via a nasal spray containing 4 IU oxytocin per spray. In total 6 sprays of oxytocin (3 per nostril) will be administered. Placebo (PLC) will consist of the vehicle fluid contained in the oxytocin nasal spray without actual oxytocin.

Study burden and risks

n/a

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

18-30 years old, male, good physical and mental health

Exclusion criteria

• History of medication within 1 month prior to the start of treatment with trial medication with exception of occasional use of paracetamol.
• Medical or surgical history that in the investigator*s view may significantly affect the outcome of the trial; such as severe visual impairment (including color-blindedness).
• Febrile illness within 3 days before the first dose.
• Participation in another drug study within 3 months preceding participation in the current study.

• Inability to understand the nature and extent of the trial and the procedures required.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	16
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	16-03-2010
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
EudraCT	EUCTR2010-018680-42-NL
CCMO	NL31495.091.10