The effects of oxytocin on trust and aggression

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- to assess the effects of intranasal administration of oxytocin in comparison to placebo on trust, as measured by the behavioural response to the Trust game- to assess the effects of intranasal administration of oxytocin in comparison to placebo on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON37316

Source
ToetsingOnline

Brief title
Behavioral effects of oxytocin

Condition

- Personality disorders and disturbances in behaviour

Synonym
aggression, antisocial behavior

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aggression, behavior, oxytocin, trust

Outcome measures

Primary outcome

Outcome measures will be:

1) points scored on the PSAP (oxytocin vs placebo)

2) points scored on the Trust Game (oxytocin vs placebo)

3) salivary levels in testosterone and cortisol

4) urinary and serum levels of oxytocin

Secondary outcome

Outcome measures on the different questionnaires:

1) Personality, as measured on the *Neuroticism-Extroversion-Openness

Inventory- Five Factor Inventory* (NEO-FFI).

2) traits of psychopathy, as measured on the *Triarchic - Psychopathy

Measure* (TriPM).

3) attachment styles, as measured on the *Relationship Questionnaire* (RQ) and

the 'Experiences in Close Relationships' vragenlijst (ECR)

4) trust, as measured on the *Trust Inventory* (TI)

5) aggression as measuren on the "agressie vragenlijst" (AVL)

6) Mood state, measured on 2 moments during the experiment, measured on the

Profile Of Mood States (POMS).

Study description

Background summary

Converging evidence reveals that oxytocin has an important role in a wide variety of behaviours. Although originally known for it*s effects on uterine contractions and lactation, oxytocin also appeared to have an effect on social behaviour like affiliation, social recognition, stress coping and aggression. Affiliative behaviours (attachment, cooperation, empathy) are critical for the psychophysiological wellbeing and normal development of individuals. Deficits in these behaviours are associated with maladaptive interpersonal and antisocial patterns and psychiatric disorders. There is substantial evidence that within the realm of aggression a disorganisation in the neural circuitry between the locus coeruleus, the amygdala and the prefrontal cortex exists, and hormonal influences and transmitters play an essential role in starting an aggressive act as a reaction to stress. Furthermore, the amygdala has an important role in recognizing expressions and, therefore, in the fear response on social cues. Oxytocin tends to down regulate the activation of the amygdala. In different animal studies, these reduced fear reactions seem to be linked to aggression. Much animal research has been done to determine the effect of oxytocin on maternal aggression. Oxytocin has an important role in the binding and protection of the newborn, thereby reducing offensive aggression, but altering defensive aggression against intruders. But also in humans, cerebrospinal fluid levels of oxytocin seem to be correlated with life history of aggression. As expected from animal studies, administering oxytocin in humans, resulted in a *tend to defend* behavior: it promoted in-group trust, cooperation and defensive behavior and a more aggressive response to competing out-groups.
In animal studies, oxytocin has been shown to diminish the natural behaviour of avoidance and promote proximity. Oxytocin down regulates the cortisol release in the HPA axis and, therefore, dampens the stress reaction. It contributes to more trust in social interactions and less fear for social betrayal.

In a forensic setting, aggression and a lack of trust of patients are essential daily problems. Patients often distrust their clinicians and are suspicious with every new part of their treatment. As a result of this, patients can react, sometimes unexpectedly, aggressive and distrustful towards their clinicians. Improved understanding of the neurobiology of aggression and trust in relation to oxytocin administration may provide challenging options for future therapeutic interventions. To clarify the extent to which oxytocin affects these measures, our first goal will be assess the behavioral and hormonal effects of oxytocin on trust and aggression in a healthy population. Research so far has mainly focused on the effects of aggression in animal studies. In this study, we want to make the first step to human research. In a double-blind placebo-controlled study, the effects of intranasal oxytocin administration will be studied during performance of a social cooperation task (Trust game) and an aggression task (Point Subtraction Aggression Paradigm) in a group of healthy males volunteers.

Study objective

- to assess the effects of intranasal administration of oxytocin in comparison to placebo on trust, as measured by the behavioural response to the Trust game
- to assess the effects of intranasal administration of oxytocin in comparison to placebo on aggression, as measured by the behavioural response to the PSAP.
- to study the relationships between serum and urine levels of oxytocin
- to study the relationships between hormonal and behavioural measures after intranasal administration of oxytocin.

Study design

This study has a randomized double-blind placebo-controlled design. According to earlier research in which oxytocin was administered to evaluate behavioural differences, we expect to need 30 participants in each group (placebo, oxytocin). We will employ a between-subject rather than within-subject design, due to the uncertainty of the learning effects of the tasks (PSAP and Trust game).
An independent statistician will provide a computer-generalised randomisation list, using block randomisation of ten participants per block. The study-pharmacist is the only one in possession of the randomisation list.

Intervention

There will be oxytocin 32IU administered or normal saline, using a nasal spray.

Study burden and risks

before the experiment, participants are asked to fill in the NEO-FFI, TriPM, TI, AVL RQ and ECR. This will take about 3 hours to complete. On the day of testing, participants will be asked to collect morning urine. In the laboratory, blood will be drawn. After this, participants will get a nasal spray with oxytocin or placebo. Oxytocin is a endogenous substance and used safely for many years under the name 'syntocinon' in woman. In men, the only reported side effects are allergic skin reactions, nausea and headache. All side effects are temporarily and are rare (in 0,01 - 0,1% of the cases according to the 'farmacologisch kompas').

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

males between the ages of 18 and 35 years, in good health, and able to understand the informed consent as assessed by the study physician.

Exclusion criteria

No mental disorder, current or past history of drug or alcohol abuse or dependence, history of hypersensitivity to oxytocin, presence of or history of clinically significant allergic rhinitis, smoke more than 10 cigarettes per day. Subjects will be excluded when they cannot understand the Dutch language sufficiently to understand the purposes and implications of the experiment.

Study design

Design

Study phase:	2
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):	01-08-2012
Enrollment:	60
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	07-08-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-11-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2012-002651-42-NL
CCMO	NL40844.078.12