The effect of oxytocin administration on empathy and emotion recognition in healthy and antisocial adolescents

Published: 29-09-2016
Last updated: 17-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON43487

Source
ToetsingOnline

Brief title
Oxytocin effect on healthy and antisocial adolescents

Condition

- Psychiatric disorders NEC

Synonym
antisocial behavior, externalizing problems

Research involving
Human

Sponsors and support

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

Intervention

Keyword: antisocial behavior, emotion recognition, empathy, oxytocin

Outcome measures

Primary outcome

The main study parameter is the difference between total scores of cognitive and affective empathy as well accuracy and reaction time of emotion recognition between conditions (oxytocin/placebo administration). Additionally, we examine whether the oxytocin effect is different between traumatized and non-traumatized antisocial adolescents by comparing the scores between groups and across conditions.

Secondary outcome

As a secondary parameter, we explore whether total scores on psychopathic traits and dissociation can moderate the oxytocin effect on empathy and emotion recognition in healthy and antisocial male adolescents. We also measure salivary oxytocin levels to examine whether baseline and after administration peripheral oxytocin is different between antisocial adolescents with and without severe psychological trauma by comparing the oxytocin levels between groups and across conditions.

Study description

Background summary

Oxytocin administration has been found to enhance empathy and emotion recognition in adults and autistic patients, but it is still unknown whether this effect is present in adolescents and especially in antisocial adolescents with severe deficits in these characteristics (empathy and emotion

recognition). However, the effect of oxytocin can be influenced by severe psychological trauma, which affects oxytocin synthesis and secretion, and dissociation or psychopathic traits which are highly prevalent in antisocial adolescents and related to abnormal oxytocin levels.

Study objective

Our primary objective is to investigate whether oxytocin administration can affect empathy and emotion recognition in healthy and antisocial adolescents. We expect that oxytocin will enhance empathy and emotion recognition in both healthy and antisocial adolescents but this effect will be attenuated in traumatized antisocial adolescents. As a secondary objective, we explore whether dissociation and psychopathic traits can moderate the oxytocin effect and whether baseline and post-administration salivary oxytocin levels differ between traumatized and non-traumatized antisocial adolescents.

Study design

Study 1 investigates the effect of oxytocin/placebo administration on empathy and emotion recognition in healthy male adolescents and Study 2 applies the same design in traumatized and non-traumatized antisocial adolescents.

Intervention

This project includes two randomized, double-blind, placebo-controlled studies with a single-dose administration of 24IU of oxytocin.

Study burden and risks

Previous reviews and meta-analyses on studies administering oxytocin in humans have revealed that oxytocin administration has no severe side-effects or adverse events for the participants and it is safe in doses 18-40 IU in research settings. The findings of the study are of paramount importance as they will provide novel evidence on the oxytocin effect on adolescents and especially antisocial adolescents, possibly leading to the development of innovative pharmacological interventions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Study 1:
-males
-age 15-18
-no current or previous psychiatric disorder as identified by the MINI-KID
-capable to read and comprehend the Dutch language
-written informed consent signed by themselves and their legal representatives;Study 2:
-Males
-age 15-18
-antisocial behavior and conduct problems as identified by the MINI-KID
-capable to read and comprehend the Dutch language
-written informed consent by themselves and their legal representatives

Exclusion criteria

-IQ lower than 75
-other severe medical problems
-medication for medical problems
-allergic responses to oxytocin
-substance abuse

-nasal surgery
-nasal disease

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):	15-03-2017
Enrollment:	256
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	29-09-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	23-03-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2016-000367-16-NL
CCMO	NL56611.000.16