

Neural mechanisms of Oxytocin in human social-emotional behaviour in males and females

Published: 13-03-2009

Last updated: 06-05-2024

To gain insight in the neurobiological mechanisms behind oxytocin effects on human social-emotional behaviour.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39969

Source

ToetsingOnline

Brief title

neural mechanisms of OT

Condition

- Other condition

Synonym

nvt

Health condition

geen, fundamenteel onderzoek

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fMRI, oxytocin, peptides, social behaviour

Outcome measures

Primary outcome

Differences in blood oxygen level dependent (BOLD) response between OT administration and placebo will be measured.

Secondary outcome

2 questionnaires

Study description

Background summary

Extensive animal literature point to a pivotal role of oxytocin in social-emotional behaviour in evolutionary distant species. This leads to the prediction that these peptides which mechanisms are at least partly conserved in humans still exert its functions in human social-emotional behaviour. An important question is to what amount these mechanisms play a role in humans. By applying oxytocin administration together with neuro-imaging we try to unravel the underlying neurobiological mechanisms in humans.

Study objective

To gain insight in the neurobiological mechanisms behind oxytocin effects on human social-emotional behaviour.

Study design

A within subjects, double blind placebo controlled OT administration study.

Intervention

The participants will self administer nasal OT spray and placebo on two separate days. The order of administration (e.g. OT on the first day/ placebo on the second day) will be counterbalanced.

Study burden and risks

Administration of OT is not known to lead to any adverse side-effects as shown in previous studies (e.g. Kosfeld et al., 2005), so it is unlikely that our participants will experience adverse phenomenological alterations. fMRI is a non-invasive technique, so there is no need for special preparation for the subject. There are no known risks associated with fMRI acquisition. If pathology is noticed, and medical treatment is indicated, the subject will be notified. The benefit of the present experiment is increased understanding of underlying neurobiological mechanisms of human social emotional processing.

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, right-handed, age between 18-30, females only using single phase oral contraceptives

Exclusion criteria

- unremovable metal in or around the body
- oversensitivity for OT or carrier
- use of psychotropic medication of recreational drugs
- alcohol use 24 prior to testing
- habitual smoking
- psychiatric treatment
- neurological treatment
- endocrinological treatment
- history of closed head injury
- history of epilepsy
- claustrophobia

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):	06-01-2012
Enrollment:	78

Type: Actual

Medical products/devices used

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

Ethics review

Approved WMO
Date: 13-03-2009
Application type: First submission
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO
Date: 05-02-2010
Application type: First submission
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO
Date: 24-04-2014
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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

EudraCT

CCMO

ID

EUCTR2008-006002-42-NL

NL25014.041.08