Oxytocin and brain responses to infant crying

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

Summary

ID

NL-OMON32632

Source
ToetsingOnline

Brief title
Oxytocin and brain responses to infant crying

Condition

- Other condition

Synonym
child acuse, emotional neglect

Health condition

child abuse/neglect

Research involving
Human

Sponsors and support

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

Intervention

Keyword: child abuse, functional Magnetic Resonance Imaging (fMRI), infant crying, oxytocin

Outcome measures

Primary outcome

Task-FMRI: signal change in emotion (regulation) regions during brain

activation.

Resting state FMRI: functional connectivity strength between brain regions at

rest.

Secondary outcome

NVT

Study description

Background summary

Studies indicate that mothers who abuse or neglect their infants show increased physiological responses to sounds of infant crying. Increased physiological responses to infant crying may involve brain mechanisms of emotion amplification and dampening. Oxytocin appears to modulate the responsiveness and balance of these brain mechanisms to stimuli such as baby crying. We aim at gaining more insight in basic mechanisms that may be involved in child maltreatment by studying effects of nasal oxytocin administration on brain responses to infant crying sounds in healthy women.

Study objective

The proposed study has two objectives. First, we will examine the neural mechanisms of aversive responding to infant cries in healthy female subjects. We will compare participants who showed high cardiovascular responses to infant cries with participants who showed low cardiovascular responses, selected from

a larger group of subjects in which such responses have already been determined. Second, the modulation of this neural mechanism by nasal administration of oxytocin will be tested.

Study design

Out of a group of 400 participants already involved in an ongoing study, 20 participants will be selected who in previous testing showed the largest cardiovascular (heart rate) responses to infant cries, and 20 participants who showed the lowest cardiovascular responses to infant cries. From each group half of the subjects will be randomly assigned to a condition in which they will be administered placebo, the other half of the subjects will be assigned to a condition in which they will be administered oxytocin. Assignment to condition will be counterbalanced according to cardiovascular responses.

Intervention

The subjects will take 6 puffs of nasal spray containing 4 IU/ puff of oxytocin (Syntocinon, Novartis), or 6 puffs of a placebo-spray (NaCl solution).

Study burden and risks

At the beginning of the session the subject will take 6 puffs of nasal spray, containing either oxytocin or a placebo. Intranasal oxytocin is widely prescribed in lactating women and is well tolerated. High doses (> 60 IU) of oxytocin nasal spray may in some cases lead to headache. Based on the single doses of 24 IU (i.e. 6 puffs, each containing 4 IU of oxytocin) that will be used in this study and the effects of oxytocin nasal spray in general, there will be low risk for the participants in this study.
There are no known risks associated with participating in an fMRI study. This is a noninvasive technique involving no catheterizations or introduction of exogenous tracers. Numerous children and adults have undergone magnetic resonance studies without apparent harmful consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of intracranial or intraocular metal, or a pacemaker. Relative contraindications include pregnancy and claustrophobia. Subjects who may be pregnant, who may have metallic foreign bodies in the eyes or head, or who have cardiac pacemakers will be excluded because of potential contraindications of MRI in such subjects. Although there is no direct benefit to the specific participants from this proposed research, there are greater benefits to society from the potential knowledge gained from this study for the targeted and effective prevention of child abuse and neglect which has been shown to be present in 30 per 1000 Dutch children in 2005.

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

female
21-55 years old

Exclusion criteria

contra-indications for fMRI (which include metal implants, heart arrhythmia, claustrophobia, and possible pregnancy)
head trauma
drug or alcohol abuse
psychiatric disorder
nasal disease or obstruction

smoking
breast feeding
oral contraceptive use.

Study design

Design

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):	22-11-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	03-11-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	26-02-2009
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-006125-13-NL
CCMO	NL24451.058.08