The effect of oxytocin on prosocial behavior in social anxiety disorder

Published: 21-11-2012
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Objective: This study hypothesizes that an oxytocin inhalation will increase prosocial behavior and reduces social anxiety during social interaction specifically in patients with SAD in comparison to a clinical and healthy control group

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON37767

Source
ToetsingOnline

Brief title
oxytocin and prosocial behavior in social anxiety

Condition

- Anxiety disorders and symptoms

Synonym
social anxiety disorder, social phobia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: oxytocin, prosocial behavior, social anxiety disorder

Outcome measures

Primary outcome

Videoraters will rate the amount of two social bonding behaviors, reciprocal self-disclosure and mimicry, and the likeability of the participants at several time-points during a 15-minutes social interaction. Participant rate their level of subjective social anxiety at several time-points during this social interaction.

Secondary outcome

Furthermore, it is examined whether SAD patients are less liked at first sight compared to a clinical and healthy control group. Last, the impact of SAD and possible oxytocin effects on economic decision-making are assessed by two short computerized tasks.

Study description

Background summary

Rationale: Patients with social anxiety disorder (SAD) are characterized by a persistent, excessive anxiety during social interactions. Recent studies indicate that they show deficits in prosocial behaviors that are essential for the development of friendships such as reciprocal self-disclosure (sharing of personal information) and mimicry (subconscious mimicking of others postures). SAD is one of the most prevalent anxiety disorders and has a great impact on quality of life. Recently is has been speculated that the hormone oxytocin plays an important role in the etiology and maintenance of SAD and in future may even develop into a medicine for treatment of this disabling disorder. Oxytocin is originally known for its role during labor and breastfeeding. Moreover, it plays an important role in the mother-child attachment. Recent studies show that this hormone also stimulates prosocial behavior in both men

as women. In addition it reduces anxiety responses. Therefore, it has been speculated that oxytocin could have a positive effect for patients with SAD. It would not only reduce their social anxiety but also stimulate pro social behavior.

Study objective

Objective: This study hypothesizes that an oxytocin inhalation will increase prosocial behavior and reduces social anxiety during social interaction specifically in patients with SAD in comparison to a clinical and healthy control group

Study design

Study design: This is a double-blind randomized placebo controlled experimental study.

Intervention

Half of the participants receive a 24 IU oxytocin inhalation and the other half with receive a placebo inhalation.

Study burden and risks

The assessment will take 4 hours. This includes an interview concerning psychopathological complaints, various questionnaires and a 15-minutes social interaction task with a confederate and two short computerized economic decision-making tasks. Participants receive either a placebo or an oxytocin inhalation. Oxytocin inhaltion are widely studied and are well tolerated.

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

Fulfill the criteria of Social Anxiety Disorder or any other Anxiety Disorder
Age between 18 and 60 years
IQ above 80
Able to read and write in Dutch
Free of medication, except hormonal contraceptives
Absence of major medical, endocrine and neurological condition

Exclusion criteria

Women: pregnancy or breastfeeding
Acute psychotic complaints, risk for suicide or automutulation
Dependent on alcohol or drugs

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	126
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	21-11-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	20-12-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20361
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-004284-75-NL
Other	is nog in behandeling
CCMO	NL38026.068.12
OMON	NL-OMON20361