Oxytocin addition to cognitive behavioural therapy in PTSD

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

Summary

ID

NL-OMON34768

Source
ToetsingOnline

Brief title
Oxytocin addition to CBT in PTSD

Condition

- Anxiety disorders and symptoms

Synonym
PTSD and stress disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Psychotraumafonds

Intervention

Keyword: CBT, Oxytocin, PTSD

Outcome measures

Primary outcome

The acute effects of oxytocin addition will be assessed by measuring change in:

heart rate (HR), heart rate variability (HRV), breathing frequency and saliva

cortisol during exposure sessions, and the change on the Subjective Units of

Distress (SUDS) during the sessions as well as the change on the Impact of

Event Scale-Revised (IES-R) from session to session.

Secondary outcome

Before and after treatment blood will be drawn from patients in both conditions

to assess the central hormone oxytocine, arginine vasopressine (AVP), and the

HPA-axis hormone cortisol.

Study description

Background summary

Posttraumatic Stress Disorder (PTSD) has a major health and economic burden on patients, their relatives and society as a whole. It is therefore important to have optimal treatment available for this disorder. Although Cognitive Behavioral Therapy (CBT) is an effective treatment for PTSD, many patients fail to attain remission with CBT. In the present study we propose to augment CBT for PTSD with oxytocin.
Given that PTSD is marked by deficits in anxiety/stress regulation and in social functioning, and that oxytocin is implicated in both these areas, oxytocin seems a likely candidate for treatment of patients with PTSD. Oxytocin has a combination of pharmacological effects that have been shown to reduce the fear response (decreasing amygdala activation, inhibiting fear response and enhancing extinction learning) and to increase social interaction (activating social reward-related brain regions increasing engagement in the therapeutic alliance). This all may result in a *sense of safety* to the client which is a

prerequisite to successful treatment of patients with PTSD.

Study objective

The main objective of this study is to assess the efficiency of oxytocin compared to placebo as an addition to the exposure sessions in the treatment of PTSD. We hypothesize that adding oxytocin to exposure in TF-CBT produces acute changes in subjective distress and physiological reactivity (e.g., increase in heart rate variability (HRV)) and fastens the reduction of PTSD-symptom levels compared to placebo addition to exposure. Secondary, we assess effect on oxytocin levels and HPA/axis hormones.

Study design

Patients will be randomized to TF-CBT + oxytocin (n = 10) or to TF-CBT + placebo (n = 10). During exposure sessions, physiological parameters, immediate subjective distress levels and PTSD symptom levels will be obtained in both conditions.

Intervention

TF-CBT with oxytocine or TF-CBT with placebo.

Study burden and risks

The burden and risks associated with participation in this study is reasonable. Participants receive Trauma-focused Cognitive Behavioural Therapy (TF-CBT), which is considered to be the most effective treatment for PTSD. Oxytocin is a relatively save drug except during pregnancy. Female patients of childbearing potential therefore must have a negative pregnancy test.

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

-CAPS score of * 50
-Age 18 years and above
-Written informed consent
-Eligible for exposure therapy

Exclusion criteria

-Suicidal risk
- Presence of any of the following DSM IV diagnoses, at present or in the past: psychotic disorder incl. schizophrenia, a bipolar disorder, depression with psychotic features, or excessive substance related disorder over the past 6 months
Female patients being pregnant (NB. female patients with childbearing potential must have a negative pregnancy test)
- Female patients with an active pregnancy wish
- Female pregnant patients (patients with childbearing potential must have a negative pregnancy test)
- Primary diagnosis of severe depressive disorder
- Presence of primary or co-morbid personality disorder
- An organic disorder
- Taking any psychotropic medications at present

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2009-017811-13-NL
CCMO	NL30877.018.09

Study results

Date completed:	01-02-2014
Actual enrolment:	2