Oxytocin in PTSD: Effectiveness in addition to NET.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28355

Source
NTR

Brief title
OPEN

Health condition

posttraumatic stress disorder (PTSD); posttraumatische stress stoornis (PTSS)

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, University of Amsterdam

Intervention

Outcome measures

Primary outcome

Primary study endpoint is the PTSD symptom level. PTSD symptoms will be assessed by means of clinical diagnostic interview (Clinician-Administered PTSD Scale, assessed before the first session and at 1-3 and 14-6 weeks post-treatment) and self-report questionnaire (Impact of Events Scale-Revised, measured at all assessment points).

Secondary outcome

Secondary study endpoints are measures of stress-reactivity, both self-reported (Perceived Stress Reactivity scale, assessed before the first session and at 1-3 and 14-6 weeks post-treatment) and physiological stress reactivity (heart rate, heart rate variability and salivary cortisol, assessed after each NET session). In addition, co-morbid depressive symptoms are a secondary endpoint. Depressive symptoms will be assessed by self-report questionnaire (Beck Depression Inventory, assessed before the first session and at 1-3 and 14-16 weeks post-treatment).

Study description

Background summary

N/A

Study objective

We expect a faster reduction (steeper curve) in the participants who receive oxytocin compared to placebo in addition to NET, as well as lower symptom levels at 1-3 weeks and 14-16 weeks post-treatment.

Study design

Assessment with clinical interviews en questionnaires takes place before the first session and at 1-3 and 14-6 weeks post-treatment. Questionnaires and biological measures are performed weekly, for 16 weeks max.

Intervention

Intranasal oxytocin (24 IU administered weekly prior to each NET treatment session for max 16 weeks), or intranasal saline placebo (6 puffs administered weekly prior to each NET treatment session for max 16 weeks).

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Eligibility criteria

Inclusion criteria

1. Patients with a diagnosis of chronic PTSD (> 3 months);

2. CAPS score of ≥ 50 ;

3. Age 18 to 65 years;

4. Written informed consent;

5. Eligible for exposure therapy
6. Capable to read and comprehend either the Dutch or English language.

Exclusion criteria

1. Suicidal risk;

2. Presence of any of the following DSM IV diagnoses, at present or in the past: psychotic disorder incl. schizophrenia, a bipolar disorder, or excessive substance related or eating disorder over the past 6 months;

3. Female patients being pregnant (NB. female patients with childbearing potential must have a negative pregnancy test each month);

4. Female patients with an active pregnancy wish;

5. Female patients giving lactation to their child;

6. Diagnosis of current severe depressive disorder (with psychotic features and/or high suicidal intent);

7. An organic disorder/cognitive impairment;

8. Patients using psychotropic medications will be required to have been on a stable dose for at least 2 months before their pre-treatment assessment (T0). Psychotropic medication already used at the pre-treatment assessment will be maintained until the post-treatment assessment. No psychotropic medication will be prescribed for participants during the study unless they develop serious depressive symptoms. A medication protocol in accordance with clinical guidelines (A.P.A., 2004; Institute of Medicine (IOM), 2008; National Institute for Clinical Excellence, 2005) will be used;

9. Use of prostaglandins and certain anti-migraine medications (ergot alkaloids), systemic glucocorticoids and beta-blockers;

10. Sensitivity or allergy for oxytocin or its components (e.g. methylhydroxybenzoaat en propylhydroxybenzoaat);

11. Evidence of clinically significant and unstable medical conditions in which OT administration is contra-indicative, including cardiovascular, gastro-intestinal, pulmonary, severe renal, endocrine or hematological disorders, glaucoma, history of epilepsy, and stroke or myocardial infarction within the past year.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-12-2012
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37116
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3566
NTR-old	NTR3724
CCMO	NL41223.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37116

Study results

Summary results
N/A