Oxytocin in PTSD: Effectiveness in addition to NET.

Gepubliceerd: 28-11-2012 Laatst bijgewerkt: 19-03-2025

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28355

Bron
NTR

Verkorte titel
OPEN

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center, University of Amsterdam
Overige ondersteuning: Academic Medical Center, University of Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-12-2012
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37116
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A