The effect of oxytocin on brain processes in PTSD.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20321

Bron
NTR

Verkorte titel
BOOSTER

Aandoening

Posttraumatic stress disorder (PTSD), Oxytocin, Neuroimaging

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome measures of this study are the acute effects of intranasal OT

administration on emotional- and reward related brain processes in men and women diagnosed with PTSD compared to traumatized healthy men and women.

Toelichting onderzoek

Achtergrond van het onderzoek

A promising candidate to improve treatment response in PTSD is the neuropeptide oxytocin (OT). OT is involved in several processes disrupted in PTSD, i.e. the fear response, social interaction and reward. In addition, OT is implicated in the pathophysiology of psychiatric disorders involving disturbed stress regulation as well as disrupted attachment and/or social deficits.

In this functional Magnetic Resonance Imaging (fMRI) study, the primary objective is to examine the acute effects of intranasal OT administration on emotional- and reward-related brain processes in PTSD patients (20 males/ 20 females) compared to traumatized healthy controls (20 males/ 20 females). Furthermore, we aim to examine gender differences in the effects of intranasal OT administration on functional (task-specific) brain activation and in structural anatomy (i.e. volume and white matter integrity) between PTSD patients and traumatized healthy controls.

Investigating the role of OT administration on emotional and reward-related processes in the brain may lead to novel strategies to improve treatment for PTSD.

Doel van het onderzoek

We expect that OT administration in PTSD patients and controls will dampen amygdala activity and increase reward sensitivity. We hypothesize to see a group by treatment interaction effect, such that the magnitude of the neural effects of OT treatment will differ between PTSD patients and controls.

Onderzoeksopzet

Two fMRI sessions, one week apart.

Onderzoeksproduct en/of interventie

One dosis of intranasal oxytocin (40 IU) and one dosis of intranasal saline placebo (10 puffs) before fMRI.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 – 65 years;

2. Capable to read and comprehend the Dutch language;

3. Eligibility for MRI;

4. Exposed to a potentially traumatic event.

PTSD patients:

1. Current PTSD diagnosis;

2. CAPS score ≥ 45.

Traumatized healthy controls:

1. CAPS-score < 15.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any severe or chronic systemic disease;

2. Current psychotic, bipolar, substance-related, severe personality disorder, or mental retardation;

3. Current severe depressive disorder;

4. Prominent current suicidal risk or homicidal ideation;

5. Severe cognitive impairment or a history of organic mental disorder;

6. History of neurological disorders (e.g. traumatic brain injury, seizure history);

7. Reports of ongoing traumatization (e.g. in case of partner violence as index adult trauma);

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

9. Use of certain medication: prostaglandins, certain anti-migraine medications (ergot alkaloids), ß-adrenergic receptor-blocking agents, systemic glucocorticoids and psychopharmacological medication;

10. Sensitivity or allergy for OT or its components (e.g. methylhydroxybenzoate and propylhydroxybenzoate);

11. Female participants: pregnancy and breast feeding (NB: female participants with childbearing potential must have a negative pregnancy test).

Traumatized healthy controls only:

1. (Lifetime history of) PTSD diagnosis, major depressive disorder;

2. Current DSM-IV axis 1 disorder.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-07-2012
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3368
NTR-old	NTR3516
Ander register	IRB AMC / EUDRA CT : 2012_085 / 2012-001288-58;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Olff, M., W. Langeland, A. Witteveen, D. Denys, 2010. A psychobiological rationale for oxytocin in the treatment of posttraumatic stress disorder. CNS spectr., v. 15, no. 8, p. 522-30.

Olff, M. 2012 Bonding after trauma: on the role of social support and the oxytocin system in traumatic stress. European Journal of Psychotraumatology 2012, 3: 18597.