Boosting oxytocin after trauma.

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

Samenvatting

ID

NL-OMON27745

Bron
NTR

Verkorte titel
BONDS

Aandoening

PTSD, trauma-related psychopathology

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Differences in PTSD symptom severity measured with the CAPS at one-and-a-half months post trauma follow-up.
fMRI substudy: brain reactivity and connectivity measures to emotional face matching and traumatic script imagery tasks.

Toelichting onderzoek

Achtergrond van het onderzoek

1-Oct-2014:

Risk factors for developing PTSD early post-trauma trauma include high initial levels of distress, a lack of social support, and dysregulations of the fear and stress system. We propose a significant role for the “bonding” hormone oxytocin in reducing adverse consequences of trauma, namely through regulating stress and fear responses and increasing the susceptibility for positive effects of social interaction. Oxytocin is synthesized and released in the presence of safe social contact and is implicated in trust and pair-bonding. In addition, oxytocin regulates fear- and stress-responses at the level of amygdala, the autonomic nervous system and hypothalamic-pituitary-adrenal axis.
In this study we will examine the effects of multiple intranasal oxytocin administrations on the development of trauma-related psychopathology symptoms, and the effects of a single oxytocin administration on brain reactivity and connectivity in recently traumatized individuals.
The results will provide unique clinical data on the role of oxytocin in psychobiological responses to trauma, crucial for the application of oxytocin in preventing or treating trauma-related disorders.

Doel van het onderzoek

We expect that oxytocin treatment alone will reduce trauma-related psychopathology at one-and-a-half month follow-up compared to participants who received placebo.
fMRI substudy: we expect that a single oxytocin administration will attenuate neural responses to threat- and trauma-related stimuli compared to placebo.

Onderzoeksopzet

CAPS scores: One and a half months post trauma follow up.
fMRI substudy: max 11 days post-trauma.

Onderzoeksproduct en/of interventie

Intranasal oxytocin (2dd 40 IU for 7 days), or intranasal saline placebo (2dd 10 puffs for 7 days). The intranasal treatments start approximately on day 9 post trauma.
fMRI substudy: a single administration of oxytocin (40 IU) or placebo (10 sprays) 45 min prior to functional MRI scanning.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presentation at the Trauma Unit or Emergency Department after a potentially traumatic event, according to PTSD A1 criterion in the DSM-IV;

2. Trauma Screening Questionnaire (TSQ) ≥ 5, or Peritraumatic Distress Inventory (PDI) ≥ 17 between 24 and 72 hours after trauma exposure;

3. Age 18 – 65 years;

4. Capable to read and comprehend either the Dutch or English language.

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. Evidence of PTSD or depression immediately prior to the index trauma;

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

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

9. 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;

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

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

12. Impaired consciousness, amnesia or confusion (due to for example head injury) (Glasgow Coma Scale lower than 13);

13. Female participants: Pregnancy and breast feeding (NB. Female participants with childbearing potential must have a negative pregnancy test);

14. fMRI substudy only: contraindications for MRI scanning.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-01-2012
Aantal proefpersonen:	220
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-11-2011
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	NL3042
NTR-old	NTR3190
Ander register	IRB AMC / EudraCT : 2011_273 / 2011-004177-83;
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.

Frijling, J. L., van Zuiden, M., Koch, S. B., Nawijn, L., Goslings, J. C., Luitse, J. S., ... & Olff, M. (2014). Efficacy of oxytocin administration early after psychotrauma in preventing the development of PTSD: study protocol of a randomized controlled trial. BMC psychiatry, 14(1), 92.