Boosting oxytocin after trauma.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27745

Source
NTR

Brief title
BONDS

Health condition

PTSD, trauma-related psychopathology

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Differences between intervention groups in depression and general anxiety symptoms, neuroendocrine and psychophysiological measures, perceived social support, and psychological functioning after one week of intranasal treatment, and on one and a half, three and six months post trauma exposure;

2. Difference in PTSD symptoms severity (CAPS scores) between the two trial arms (i.e. OT and
placebo) at three and six months post trauma follow-up;

3. Potential associations between the main study outcomes and gender, genetic variation, subjective measures of social support, representations of attachment style, coping style, subjective health complaints, affect, quality of life, trauma type, and history of (childhood) trauma and life events.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2012
Enrollment:	220
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-11-2011
Application type:	First submission

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
NTR-new	NL3042
NTR-old	NTR3190
Other	IRB AMC / EudraCT : 2011_273 / 2011-004177-83;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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.