Fathers Today: The Role of Hormones in Father's Sensitive and Protective Parenting

No registrations found.

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

Summary

ID

NL-OMON25106

Source
NTR

Brief title
Fathers Today

Health condition

hormones, fathers, parenting, neuroimaging

Sponsors and support

Primary sponsor: ERC (Horizon 2020), Spinoza (NWO)
Source(s) of monetary or material Support: The present study is funded by an European Research Council (ERC) Advanced Grant (AdG) (ERC AdG 669249) awarded to M.J. Bakermans-Kranenburg and a Spinoza prize awarded to Marnius H. van IJzendoorn.

Intervention

Outcome measures

Primary outcome

Primary outcome:

We will examine the effects of oxytocin and vasopressin administration on quality of infant-father interactions, protective paternal behaviors, and use of handgrip force when fathers listen to infant cry sounds

Secondary outcome

Secondary outcome:

We will examine the effects of oxytocin and vasopressin administration on the neural processing of infant cry sounds and threat to the infant.

Tertiary outcome:

We will examine the moderating effects of fathers' early childhood experiences.

Study description

Background summary

Summary:

Whereas previous research has mostly focused on the hormonal, behavioral and neural correlates of maternal caregiving, the present study will examine the hormonal, behavioral, and neural dynamics of paternal behavior in first-time fathers during a specific phase of fatherhood: between 2 and 7 months after the baby has been born. The study includes a randomized, double-blind, placebo-controlled within-subject design to examine the effects of intranasal administration of oxytocin and vasopressin on parenting behavior and the neural and behavioral responses to infant signals. In addition, we will examine whether effects of oxytocin and vasopressin are moderated by fathers' early childhood experiences.

Study population:

A total of 55 first-time fathers of a child aged between 2 and 7 months old will visit our lab for three experimental sessions. The experimental sessions include the following conditions: intranasal administration of (1) oxytocin, (2) vasopressin, and (3) a placebo. Participants will be randomly assigned to order of administration. Participants and researchers are blind to order of administration. The experimental sessions will take place with intervening periods of 1 to 2 weeks.

Intervention:

Participants are randomly assigned to one of the six counterbalanced orders of conditions. Participants are instructed to self-administer oxytocin (Syntocinon®, 24 IU/ml, registered in the Netherlands as RVG 03716), vasopressin (Vasostrict®, 20 IU/ml), or placebo (Chlorbutanol solution) using a nasal spray. Self-administration takes place under supervision

of a researcher blind to condition. All experimental medication is prepared by the hospital pharmacy of the Amsterdam University Medical Centre. Randomization of administration is performed by an independent researcher who is not involved in the study. Randomization is performed before the start of the interventions using a computer-generated randomization sequence. Researchers and participants are blind to order of assignment.

Study objective

Our primary hypotheses are:

1. We hypothesize that infant-father interactions in the oxytocin and vasopressin condition are characterized by enhanced stimulatory and sensitive play and increased paternal protective behavior as compared to the placebo condition.
2. We expect that oxytocin and vasopressin administration affect behavioral responses to infant cry sounds and neural responses to infant cry sounds and threat to the infant.

Study design

Participants will visit our research centrum for three experimental sessions.

Intervention

Administration of oxytocin, vasopressin, and placebo. Participants are randomly assigned to one of the six counterbalanced orders of conditions.

Contacts

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Eligibility criteria

Inclusion criteria

Fathers having their first baby, child’s age = 2-7 months; living in the same house as their partner and the baby. Both parents must have parental authority.

Exclusion criteria

History of or current neurological disorders, endocrine diseases, psychiatric disorders, cardiovascular diseases, use of psychoactive medications, nose injuries and disorders, or magnetic resonance imaging contraindications.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2019
Enrollment:	55
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	30-10-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48305
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8124
CCMO	NL70143.058.19
OMON	NL-OMON48305

Study results

Summary results
N/A