The role of oxytocin on placebo/nocebo effects in a pain conditioning paradigm.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45392

Source
ToetsingOnline

Brief title
Oxytocin and placebo/nocebo effects

Condition

- Other condition

Synonym
not applicable

Health condition

Het onderzoek wordt bij gezonde personen uitgevoerd. Het onderzoek kan voor nieuwe inzichten zorgen bij therapeutische interventies voor pijn.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: ERC Consolidator Grant

Intervention

Keyword: nocebo, oxytocin, pain, placebo

Outcome measures

Primary outcome

The main study parameter is a difference between the oxytocin and placebo groups in the placebo effect. The placebo effect will be calculated as the difference in the subjective pain ratings between the yellow (control) and green (placebo) cues in the heat pain conditioning task in the testing phase.

Secondary outcome

The secondary study parameter is the difference between the groups in the nocebo effect. The nocebo effect will be calculated as a difference in the subjective pain ratings between the red (nocebo) and yellow (control) cues in the heat pain conditioning task in the testing phase.

Study description

Background summary

Placebo and nocebo effects have been repeatedly shown to be able to respectively relief or worsen symptoms of a variety of diseases such as pain, depression, anxiety, addiction, and Parkinson*s disease amongst others. Despite an increasing body of literature on placebo effects, it is currently not yet clear how we can maximize placebo effects in order to obtain the best therapeutic results and how to weaken the nocebo effects to reduce the side effects of medications. Oxytocin administration may potentially enhance the placebo effect by reducing anxiety, increasing trust and stimulating the secretion of nitric oxide that has been shown to mediate the placebo response.

Only few studies have been performed in this important area with conflicting evidence.

Study objective

The primary objective is to investigate whether exogenous oxytocin administration enhances the placebo effect of as measured by subjective pain intensity to a previously validated heat pain conditioning task. In addition, we will explore the effects of oxytocin on the nocebo effect.

Study design

A randomized, placebo-controlled study design will be used. Participants will be randomly allocated to one of two groups: 1) oxytocin group or 2) placebo group. First, three levels of heat stimulation will be determined for each participant individually which will be used in the pain conditioning task: 1) a temperature that elicits low pain (pain detection threshold, equal to around 1 on the 10 numeric rating scale (NRS); low pain), temperature that elicits mild to moderate levels of pain (equal to around 4 on the 10 NRS, mild pain) and temperature that elicits moderate to high but bearable levels of pain (equal to around 7 on the 10 NRS; moderate pain). Afterwards, participants in the oxytocin group will receive 40 IU of intranasal oxytocin spray; participants in the placebo group will receive the same volume of a placebo spray. In 30 minutes of waiting time the heat pain conditioning task with conditioning and testing phases will be performed. Participants in both groups will receive 66 repeated pairings of visual stimuli and pain stimulations and a subjective pain ratings will be measured. Each stimulus will have a peak temperatures lasting for 4 seconds.
The experiment will be concluded with filling out several questionnaires and participants will be debriefed and provided a chance to ask questions about the experiment and their participation.

Intervention

In the oxytocin group, participants will receive a 40 IU dose of oxytocin via a nasal spray. In the placebo group, participants will receive a placebo spray. The placebo and nocebo effects will be induced by a conditioning procedure using visual cues and sham electrodes while heat stimuli are delivered.

Study burden and risks

Study duration will be around 1,5 hours. The study population will consist of healthy volunteers, therefore, no serious side effects are expected in the current study. Several studies have been conducted in humans with repeated doses up to 80 IU of oxytocin without reporting side effects. One time administration of 40 IU of oxytocin is considered to be a safe and effective

dose.
The standardized pain application device (ATS-II, Medoc Advanced Medical Systems, Ramat Yishai, Israel) has built-in safeguards and was safely used in numerous studies on pain stimulation and pain conditioning, including in an ongoing study of our own group (P15.071). All other measurements are minimally invasive.
Participants will receive a reimbursement of 15 euros for participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Men between 18 and 35 years old

- Good understanding of written and spoken English

Exclusion criteria

- Refusal to give written informed consent
- Conditions that might interfere with the participant's safety and/or the study protocol: severe somatic or psychological morbidity (e.g., heart and lung diseases, or DSM-IV psychiatric disorders)
- Family history of an acute heart failure or death caused by an acute heart failure
- Chronic or acute pain complaints
- Current use of analgesics

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2017
Application type:	First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL60185.058.16