Oxytocin and placebo/nocebo effect

No registrations found.

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

Summary

ID

NL-OMON25836

Source
NTR

Brief title
Oxytocin and placebo/nocebo effect

Health condition

Placebo effect in healthy subjects

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: European Research Council Consolidator Grant

Intervention

Outcome measures

Primary outcome

To investigate whether exogenous oxytocin administration enhances the placebo effect, the oxytocin and control groups will be compared on the difference between subjective pain ratings between the yellow (control) and green (placebo) cues in the heat pain conditioning task in the first part of the testing phase.

Secondary outcome

To investigate the effects of exogenous oxytocin administration on nocebo effect, the oxytocin and control groups will be compared on the difference between subjective pain ratings between the red (nocebo) and yellow (control) cues in the heat pain conditioning task in the first part of 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 (Benedetti, 2008; Benedetti et al., 2003, Wolkov et al., 2003). 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. The primary objective of the current study is to investigate whether exogenous oxytocin administration enhances the placebo effect of classical conditioning and verbal suggestions as measured by subjective pain intensity to a previously validated heat pain conditioning task. In addition, the effects of oxytocin on nocebo effect will be explored.

Study objective

The primary objective is to investigate whether exogenous oxytocin administration enhances the placebo effect of classical conditioning and verbal suggestions as measured by subjective pain intensity to a previously validated heat pain conditioning task. We hypothesize that oxytocin will enhance the placebo effect as induced by positive verbal suggestions and conditioning procedure. In addition, we will explore the effects of oxytocin on the nocebo effect.

Study design

The study consists of one session in which the heat pain conditioning task is performed once.

Intervention

A randomized, placebo-controlled study design will be used. After an initial screening, participants will take part in one study visit. First, participants will be randomly allocated to one of two groups: 1) oxytocin group or 2) control group. Participants in the oxytocin group will receive 40 IU of intranasal oxytocin spray; participants in the control group will receive the same volume of a placebo spray. Then 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 (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). Pain stimuli will be applied to the dorsal site of the left arm with an ATS thermode (ATS-II, Medoc Advanced Medical Systems, Ramat Yishai, Israel) with a peak temperature lasting for 4 seconds. Subsequently, 30 minutes after the spray administration, when the oxytocin effects are assumed to be peaking (MacDonald & MacDonald, 2010), the heat pain conditioning task will be performed. This task consists of two phases: a learning phase and a testing phase. In the learning phase, a green light will be coupled to a low pain stimulus (placebo condition), a yellow light to a mild pain (control condition) and a red light to a moderate painful stimulus (nocebo condition). In addition, a sham electrode will be attached to the hands of participants and they will be told that the green light activates a mode of the electrode that has an analgesic effect and the red light will indicate the activation of the mode of the electrode that increases pain. In the test phase, only mild pain will be given while learned associations to coloured lights will be tested. After each pain stimulus, participants will be asked to rate the pain intensity on a 0 (no pain) - 10 (most intense pain imaginable) NRS.

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.

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Eligibility criteria

Inclusion criteria

1. Healthy male volunteers between 18 and 35 years old;

2. Good understanding of written and spoken English.

Exclusion criteria

1. Current psychiatric (DSM-IV) conditions;

2. All conditions that might interfere with the participant's safety and/or the study protocol: e.g., severe somatic or psychological morbidity (e.g., heart and lung diseases, low blood pressure, family history of an acute heart failure or a death due to an acute heart failure, DSM-IV psychiatric disorders, and current use of analgesics drugs)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2017
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	08-06-2017
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	NL6008
NTR-old	NTR6506
Other	METC LUMC : P16.319

Study results