Enhancing placebo effects in pain and itch through oxytocin

Published: 23-03-2016
Last updated: 15-05-2024

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

Summary

ID

NL-OMON42756

Source
ToetsingOnline

Brief title
Placebo effects and oxytocin

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 en jeuk.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: itch, oxytocin, pain, placebo

Outcome measures

Primary outcome

The main study parameters are self-reported pain in response to the Cold

Pressor Test and self-reported itch in response to the histamine iontophoresis.

Secondary outcome

Secondary parameters are skin temperature, flare response, and wheal size in

response to the histamine iontophoresis, unpleasantness ratings in response to

the Cold Pressor Task. Furthermore, the possible influence of psychological

parameters on outcomes will be explored as well.

Study description

Background summary

Placebo effects have been demonstrated to decrease pain and itch by means positive suggestions. It is of high clinical relevance to find ways to maximize placebo effects in order to obtain the best therapeutic results. Oxytocin administration may potentially enhance the placebo effect but few studies have been performed in this important area with conflicting evidence for pain and no studies for itch.

Study objective

The primary objective is to investigate whether exogenous oxytocin administration enhances the placebo effect of positive suggestions as measured by subjective pain intensity and itch ratings in response to validated pain (Cold Pressor Test) and itch-inducing (histamine iontophoresis) tasks.

Secondary objectives are to investigate the effects of oxytocin administration combined with specific positive verbal suggestions on:
* Pain unpleasantness ratings during the Cold Pressor Test
* Skin temperature, flare response, and wheal size in response to histamine iontophoresis.
* Positive and negative affect
* Pain and itch expectations

Study design

A randomized placebo-controlled, study design will be used. Participants will be randomly allocated to one of four groups: 1) oxytocin group with positive suggestions, 2) oxytocin group without positive suggestions, 3) placebo group with positive suggestions, 4) placebo group without positive suggestions. Participants will perform a baseline Cold Pressor Test and their pain sensitivity, pain sensitivity threshold, pain tolerance threshold, and unpleasantness ratings will be measured. Subsequently, participants will be administered oxytocin or placebo spray and participants in two groups (oxytocin with suggestions group and placebo with suggestions group) will receive positive verbal suggestions about analgesic and itch-relieving effects of oxytocin. After a waiting period for the oxytocin to take effect, the second Cold Pressor Test will be done and the same parameters will be measured. The session will finish with transdermal histamine iontophoresis. Itch ratings, wheal size, and skin temperature will be measured.

Intervention

In the oxytocin with suggestions and oxytocin without suggestions groups, participants will receive a 24 IU dose of oxytocin via a nasal spray. In the placebo groups, participants will receive a placebo spray. The placebo effect will be induced by positive suggestions about analgesic and itch-relieving properties of the spray.

Study burden and risks

Participants need to invest a total of 1,5 hours in the study. No adverse 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 adverse side effects. One time administration of 24 IU of oxytocin is considered to be a safe and effective dose. The Cold Pressor Test has been used in numerous studies with a maximum immersion time of 5 minutes or more. In the current study participants may withdraw their hand from the cold water any time they wish with the maximum immersion of 1 minutes. The symptoms of transdermal histamine iontophoresis (local swelling, itch, and flare) will disappear within several minutes to a maximum of 2 hours; it has been used in numerous studies without adverse effects. All other measurements

are considered minimally invasive. Participants will receive a reimbursement of 12,50 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

- Female between 18 and 35 years old
- Good understanding of written and spoken Dutch

Exclusion criteria

- Refusal to give written informed consent

- Pregnancy or breast feeding
- 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, Raynaud*s phenomenon)
- Chronic or acute itch or pain complaints
- Current use of analgesics, anti-inflammatory drugs, antihistamines, antibiotics

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2016
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

ID: 27820
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL55922.058.15
OMON	NL-OMON27820