# Oxytocin and the placebo effect.

No registrations found.

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

## Summary

### ID

NL-OMON27820

**Source**
NTR

**Brief title**
Oxytocin

**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**

The main study outcome is the difference between the oxytocin with positive suggestions group (group 1) and the placebo with positive suggestions group (group 3) on self-reported pain ratings and on self-reported itch ratings. Self-reported pain will be assessed in response to the CPT after the intervention controlled for the baseline CPT self-reported pain ratings. Self-reported itch ratings will be assessed in response to HI.

### Secondary outcome

• The difference between the oxytocin without positive suggestions group (group 2) and the placebo without positive suggestions group (group 4) on self-reported pain and itch ratings in response to the CPT and histamine test to investigate the effects of oxytocin on pain and itch sensitivity

• The difference between the placebo with positive suggestions group (group 3) and placebo without positive suggestions group (4) on self-reported pain and itch ratings in response to the CPT and histamine test to investigate the effects of verbal suggestions on pain and itch sensitivity

## Study description

### Background summary

Placebo effects have been demonstrated to decrease pain and itch by means of 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 of positive suggestions but few studies have been performed in this important area with conflicting evidence for pain and no studies for itch so far. The primary objective of the current study is to investigate whether exogenous oxytocin administration enhances the placebo effect induced by 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. In addition, the effects of oxytocin on pain sensitivity and the effects of positive verbal suggestions on pain sensitivity are investigated as secondary outcome parameters. Finally, the influence of expectations, affect and personality characteristics are explored.

### Study objective

The primary objective of the current study is to investigate whether exogenous oxytocin administration enhances the placebo effect induced by 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. We hypothesize that oxytocin will enhance the placebo effect as induced by positive verbal suggestions.

### Study design

The study consists of one session in which CPT is performed twice and HI is performed once.

### Intervention

A randomized, placebo-controlled study design is used. After initial screening, participants take part in one study visit in which they are 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 perform a baseline CPT (Cold Pressor Test) on which their pain sensitivity and unpleasantness ratings are measured. Subsequently, participants are administered an oxytocin or placebo spray. In the oxytocin with positive suggestions and oxytocin without positive suggestions groups, participants receive a 24 IU dose of oxytocin via a nasal spray. In the placebo groups, participants receive a placebo spray. Participants in two groups (oxytocin with positive suggestions group and placebo with positive suggestions group) additionally receive positive verbal suggestions about the expected analgesic and itch-relieving effects of oxytocin. After a waiting period for the oxytocin to take effect, a second CPT is performed. The session finishes with transdermal HI (histamine iontophoresis) after which itch ratings, wheal size, and skin temperature are measured. Additionally, questionnaires are administered to assess positive and negative affect, personality and expectations amongst others.

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## Eligibility criteria

### Inclusion criteria

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

2. Good understanding of written and spoken Dutch.

### 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., Raynaud’s phenomenon, severe neurological or neurosurgical conditions;

3. (Intended) pregnancy or breast feeding.

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 08-04-2016 |
| Enrollment: | 108 |
| Type: | Actual |

## Ethics review

Positive opinion

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| Date: | 31-01-2017 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 42756
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL6212 |
| NTR-old | NTR6376 |
| CCMO | NL55922.058.15 |
| OMON | NL-OMON42756 |

# Study results

**Summary results**
n/a