Conditioning Antihistamine

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27241

Bron
NTR

Verkorte titel
Conditioning Antihistamine

Aandoening

Itch, conditioning;
Jeuk, conditioneren

Ondersteuning

Primaire sponsor: Leiden University
Overige ondersteuning: European Research Council Consolidator Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameter is the difference in self-reported mean itch during a validated histamine test (iontophoresis) between the conditioned groups and the placebo group. Itch will be assessed by means of a numeric rating scale (NRS).

Toelichting onderzoek

Achtergrond van het onderzoek

In the present study, the effects of behavioural conditioning on self-reported itch are studied in a closed versus open label conditioning paradigm. In a randomized controlled trial, participants will be screened and following inclusion allocated to one of four study groups. The conditioning paradigm consists of two phases. In the acquisition phase – consisting of 3 sessions on 3 consecutive days – an association between an unconditioned stimulus (UCS, levocetirizine) and a conditioned stimulus (CS, a distinctive-tasting drink) will be made. In the evocation phase – 3 consecutive days in the following week – it will be tested whether presenting the CS alone will evoke the conditioned effect. It is expected that conditioning will lead to a reduction in reported itch following a short-term validated histamine test. Secondary outcomes include effects on psychophysiological measurements, for example pulmonary functioning, wheal size, flare response, and scratching behaviour.

Doel van het onderzoek

The aim of the study is to investigate the effect of behavioural conditioning on self-reported itch in response to a short-term validated histamine test in healthy participants. Additionally, the study will explore the efficacy of open label conditioning (i.e. being told about the conditioning procedure) in a closed vs. open label design, the latter of which is more related to clinical practice. It is expected that conditioning will lead to a reduction in self-reported itch following a short-term validated histamine test.

Onderzoeksopzet

The study consists of 7 sessions during the course of 3 weeks. In the first week, participants will be screened for medical and psychological conditions. In the second week, the acquisition phase - consisting of 3 sessions on 3 consecutive days - takes place and in the final week during the evocation phase - again consisting of 3 consecutive sessions - the conditioned response will be tested.

Onderzoeksproduct en/of interventie

In line with previous conditioning studies, a randomised placebo-controlled conditioning paradigm consisting of 2 phases will be applied. In the acquisition phase - consisting of 3 sessions on 3 consecutive days - an association between an unconditioned stimulus (UCS, levocetirizine diHCl) and a conditioned stimulus (CS, a distinctive-tasting drink) will be made. In the evocation phase - 3 consecutive days in the following week - the conditioned effect will be tested.
Participants will be randomly assigned to 1) the experimental closed label group (acquisition: CS+UCS; evocation: CS+placebo pill), 2) the experimental open label group (acquisition: CS+UCS; evocation: CS+placebo pill), 3) the placebo group (acquisition: CS+placebo pill; evocation: CS+placebo pill), or 4) the conditioned not evoked group (acquisition: CS+UCS;

evocation: water+placebo pill).
In the experimental closed label group, participants will be conditioned through repeated pairing of the administration of the distinctive-tasting drink (CS) and levocetirizine diHCl (UCS)in the acquisition phase. In the evocation phase, the conditioned effect will be tested by receiving the distinctive-tasting drink in combination with a placebo pill. In the experimental open label group, the same procedure will be applied as in the experimental closed label group, but participants will receive additional information about their group allocation and the conditioning procedure. The placebo group will receive the CS and a placebo pill throughout the acquisition and evocation sessions. To control for residual effects of levocetirizine diHCl during the evocation phase, participants in the conditioned not evoked group will receive the CS and levocetirizine diHCl in the acquisition sessions and, in the evocation sessions, will receive water and a placebo pill to prevent invoking conditioned responses through re-exposure to the CS.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Between 18 and 35 years old;

2. Good understanding of written and spoken Dutch;

3. Healthy, or if allergic, no current or recent allergic symptoms

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current psychiatric (DSM-IV) conditions;

2. All somatic conditions that might interfere with the participant’s safety and/or study protocol (e.g. asthma);

3. Recent use of antihistamines, anti-inflammatory medication, antibiotics, or recent vaccinations;

4. Current or recent (within the past 3 months) allergic symptoms, e.g. rhinitis, conjunctivitis;

5. Sensitivity to levocetirizine diHCl or any other substance used in the experiment;

6. Lactose intolerance

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-10-2015
Aantal proefpersonen:	92
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-10-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42660
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5254
NTR-old	NTR5544
CCMO	NL52687.058.15
OMON	NL-OMON42660

Resultaten

Samenvatting resultaten
n/a