Conditioning of antihistaminergic effects

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The primary study objective is to investigate effects of conditioning on self-reported itch in healthy subjects in response to a short-term validated histamine test. Conditioning effects on other physiological and psychological parameters will be...

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

Summary

ID

NL-OMON42660

Source
ToetsingOnline

Brief title
Conditioning antihistamine

Condition

- Other condition

Synonym
Not applicable

Health condition

Het onderzoek wordt bij gezonde proefpersonen uitgevoerd. Uitkomsten uit deze lijn van onderzoek bieden nieuwe handvatten voor verklaringsmodellen en therapeutische interventies voor allergene aandoeningen waarbij een verandering in de histaminerespons optreedt.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Antihistamine, Conditioning, Itch, Psychophysiological parameters

Outcome measures

Primary outcome

The primary study parameter is self-reported mean itch during histamine iontophoresis.

Secondary outcome

Secondary study parameters include the immediate inflammatory response (e.g., cytokines), bronchodilation, wheal size, flare response, skin temperature, and self-reported skin condition, and scratching behaviour following histamine iontophoresis, skin conductance and heart rate, and self-reported wellbeing. The possible influence of genetic variants (e.g. the 5HTTLPR-genotype) and of psychological factors on conditioning will be explored.

Study description

Background summary

The current evidence suggests that it might be possible to condition the effects of antihistamines, which may lead towards reduction of symptoms and improvement of quality of life in allergic patients. Discovering the psychoneuroimmunological mechanisms involved in this process could provide a basis for new therapeutic possibilities and therapies.

Study objective

The primary study objective is to investigate effects of conditioning on self-reported itch in healthy subjects in response to a short-term validated histamine test. Conditioning effects on other physiological and psychological parameters will be investigated as well and the possible influence of genetic variants such as the 5HTTLPR-genotype on conditioning will be explored.

Study design

In line with previous conditioning studies and with other studies conducted by our research group, a randomized 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) and a conditioned stimulus (CS, a distinctive-tasting beverage) will be made. In the evocation phase - 3 consecutive days in the following week - the conditioning effect will be tested.

Participants will be randomly assigned to 1.) the experimental condition (acquisition: CS + UCS; evocation: CS + placebo pill), 2.) the open label condition (acquisition: CS + UCS; evocation: CS + placebo pill), 3.) the placebo condition (acquisition and evocation: CS + placebo pill) or 4.) the conditioned not evoked group (acquisition: CS + UCS; evocation: water + placebo pill).

Bronchodilation and self-reported wellbeing will be measured repeatedly, and heart rate and skin conductance continuously during the evocation sessions. Prior to conditioning and during the final evocation session, participants will be exposed to histamine through transdermal iontophoresis, which will induce a short-term skin response and itching sensation. Additionally, the study will explore whether conditioning of antihistaminergic effects influences blood serum levels of cytokines and other markers of the immediate inflammatory response.

Intervention

Conditioning takes place in the first 3 days of the acquisition phase, i.e. in the experimental, open label and conditioned not evoked groups, Histamine-1 receptor responsiveness to histamine will be suppressed by administration of the oral antihistamine levocetirizine (5 mg). In the open label group, participants will additionally be told about the conditioning procedure and which group they are in.

Study burden and risks

Participants need to invest a total of 8 hours into the study, spread out over 7 sessions varying from 15 minutes (acquistion sessions) to 2,5 hours (final

evocation session). Given the nature, dosage, restricted number of days of administering, the relatively short half-life of levocetirizine and the healthy study population, no adverse side effects are expected. Blood sampling at the first and final session will be performed by trained medical personnel with access to hospital facilities. The symptoms of transdermal histamine iontophoresis (local swelling, itch, and flare) will disappear within two hours. All other measurements are considered minimally invasive. Participants will receive a total reimbursement of ¤ 150,00 for the 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

Between 18 and 35 years old; healthy, or when allergic, no current allergic rhinitis or allergic conjunctivitis symptoms

Exclusion criteria

Somatic and/or psychiatric conditions (e.g. asthma), recent infection, recent use of medication (excluding oral contraceptives), recent vaccinations, current or recent (within past 3 months) allergic rhinitis or allergic conjunctivitis symptoms, any allergic condition other than allergic rhinitis or conjunctivitis, sensitivity to any substance used in this study

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):	27-10-2015
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-07-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	11-08-2015
Application type:	Amendment
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: 27241
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52687.058.15
OMON	NL-OMON27241