1% capsaicin solution pain model

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20584

Source
Nationaal Trial Register

Brief title
CHDR1830

Health condition

Neuropathic pain

Sponsors and support

Primary sponsor: CHDR
Source(s) of monetary or material Support: CHDR

Intervention

Outcome measures

Primary outcome

-To determine the effect of topical capsaicin on primary hyperalgesia, as assessed by the thermal heat pain test (pain detection thresholds (PDTs))
-To determine the effect of topical capsaicin on the area of secondary mechanical allodynia, as assessed with Von Frey filaments (mm2)

Secondary outcome

-To determine the feasibility of measuring secondary hyperalgesia using LEPs
-To determine the intra-individual reproducibility of primary and secondary hyperalgesia/ allodynia measurements with Von Frey, LEPs and thermal heat pain.
-To assess the feasibility of incorporating the topical 1% ethanolic capsaicin pain model in the PainCart test battery
-To evaluate the effect of capsaicin application on psychophysical, electrophysiological and PainCart parameters

Study description

Background summary

PainCart, a test battery of human evoked pain models, is able to provide biomarkers for nociceptive and inflammatory pain in healthy volunteers, at early stages of drug development. CHDR is seeking to expand the PainCart with a model to robustly assess central sensitization, by utilizing the concept of inducing secondary hyperalgesia on an area surrounding injured, or sensitized skin. A frequently used model to induce sensitization, is topical application of capsaicin.The proposed study aims to validate the use of an ethanolic formulation of capsaicin for topical application, to assess allodynia and (secondary) hyperalgesia.

Study objective

The PainCart is a test battery of human evoked pain models which is able to measure biomarkers for nociceptive and inflammatory pain at early stages of drug development in healthy volunteers. As such, this method can be utilized as a decision making tool for pharmaceutical companies in order to determine Proof-of-Pharmacology and to guide dose selection. To be able to deploy the most elaborate test battery possible, it is essential to continue optimizing the PainCart and its evoked pain models. Introduction of a model for neuropathic pain would be a
potential improvement. This will lead to a more all-round test battery, and increases the sensitivity and selectivity of the test battery, by stimulating a pain pathway that is novel to the PainCart.

Study design

• Screening (up to 42 days before first treatment period)
• 2 treatment periods, each spanning one full day (no nights)
• Follow-up by telephone (5-9 days after second treatment period)

Intervention

1% capsaicin ethanolic solution, applied topically on the volar forearm

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male subjects, 18 to 45 years of age, inclusive. Healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical and surgical history, a complete physical examination including vital signs.
2. Body mass index (BMI) between 18 and 30 kg/m2, inclusive.
3. Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

1. History or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder.
2. Clinically significant abnormalities, as judged by the Investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis). In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
3. History of alcohol or drug abuse
4. Participation in an investigational drug or device study within 3 months prior to screening.
5. Any confirmed significant allergic reactions (urticaria or anaphylaxis) after previous exposure to capsaicin
6. Subject indicating intolerable pain after capsaicin administration at screening
7. Any current, clinically significant, known medical condition in particular any existing conditions that would affect sensitivity to cold (such as atherosclerosis, Raynaud’s disease, urticaria, hypothyroidism) or pain (i.e., disease that

causes pain, hypesthesia, hyperalgesia, allodynia, paraesthesia, neuropathy)
8. Subjects indicating pain tests intolerable at screening or achieving tolerance at >80% of maximum input intensity for any pain test for cold, pressure and electrical tests.
9. Dark skin (Fitzpatrick skin type V - VI), wide-spread acne, tattoos or scarring on the volar forearms.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	29-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48384
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7704
CCMO	NL68698.056.19
OMON	NL-OMON48384

Study results