1% capsaicin solution pain model

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20584

Bron
Nationaal Trial Register

Verkorte titel
CHDR1830

Aandoening

Neuropathic pain

Ondersteuning

Primaire sponsor: CHDR
Overige ondersteuning: CHDR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

• 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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	29-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48384
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten