Pharmacological effects on nerve excitability in healthy volunteers

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

Samenvatting

ID

NL-OMON25429

Bron
Nationaal Trial Register

Verkorte titel
CHDR1834

Aandoening

• Pain

Ondersteuning

Primaire sponsor: • Centre for Human Drug Research, Leiden
Overige ondersteuning: • CHDR investigator initiated study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pharmacodynamic endpoints:

- Nerve excitability threshold endpoints

Toelichting onderzoek

Achtergrond van het onderzoek

Neuronal excitability is largely dependent on voltage-gated sodium and potassium channels. In this study, we will investigate the effects of two drugs that inhibit the sodium channels, namely mexiletine and lacosamide, on nerve excitability and evoked pain tests in healthy subjects.
Measurement of peripheral nerve excitability would be an interesting biomarker for the efficacy of current and new treatments that influence the nerves. In this study we will validate nerve excitability threshold tracking, a measurement technique for neuronal excitability. The placebo-controlled mexiletine and lacosamide administration should inform us about the sensitivity of threshold tracking to sodium channel blockade and will serye as a benchmark for future studies with selective sodium channel
blockers. Additionally, the effect of sodium channel blockers on evoked pa¡n tests, namely the PainCart test battery and intra-epidermal
electrical stimulation (IES), will be investigated.

Doel van het onderzoek

In this study we will validate nerve excitability threshold tracking, a measurement technique for neuronal
excitability. The placebo-controlled mexiletine and lacosamide administration should inform us about the sensitivity
of threshold tracking to sodium channel blockade and will serve as a benchmark for future studies with selective
sodium channel blockers. Measurement of peripheral nerve excitability would be an interesting biomarker for the
efficacy of current and new treatments that influence nerve excitability.

Onderzoeksopzet

• 3 identical study visits

Onderzoeksproduct en/of interventie

Lacosamide / Mexiletine

Contactpersonen

Publiek

NA

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Wetenschappelijk

NA

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Signed informed consent prior to any study-mandated procedure
2. Healthy male subjects, 18 to 45 years of age, inclusive at screening.
3. Body mass index (BMI) between 18 and 30 kg/m2, inclusive at screening and with a minimum weight of 50 kg. .
4. Has the ability to communicate well with the Investigator in the Dutch language and willing to comply with the
study restrictions.
5. All subjects must practice effective contraception during the study and be willing and able to continue
contraception for at least 90 days after their last dose of study treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Evidence of any active or chronic disease or condition that could interfere with, or for which the treatment of which might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in theopinion of the investigator (following a detailed medical history, physical examination, vital signs (systolic and diastolic blood pressure, pulse rate, body temperature) and 12-lead electrocardiogram (ECG)). Minor deviations from the normal range may be accepted, if judged by the Investigator to have no clinical relevance.
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). Subjects with pre-dose findings of clinically significant changes in electrolytes should be excluded. 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. Positive Hepatitis B surface antigen (HBsAg), Hepatitis C antibody (HCV Ab), or human immunodeficiency virus antibody (HIV Ab) at screening.
8. Participation in an investigational drug or device study within 3 months prior to first dosing, or for more than 4 times a year
17. 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 (disease that causes pain, hypesthesia, hyperalgesia, allodynia, paraesthesia, neuropathy, etc.).
18. 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.
19. History or presence of post-inflammatory hyperpigmentation.
20. Dark skin (Fitzpatrick skin type IV, V or VI), widespread acne, freckles, tattoos or scarring on the back.
22. History of trauma to the upper extremities or other orthopaedic conditions that, in the opinion of the
investigator, could affect the electrophysiological measurements.
23. History of (or symptoms indicating presence of) carpal tunnel syndrome.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-08-2019
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7327
NTR-old	NTR7543
Ander register	Stichting BEBO : CHDR1834 / NL67037.056.18 / 2018-003154-24

Resultaten

Samenvatting resultaten
NA