A study in healthy volunteers to determine the repeatability of a test battery and the intra-dermal capsaicin model.

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The QST battery of the DFNS (Rolke 2006) is a comprehensive measurement for neurosensory function. The current study is a phase 0 study to assess the repeatability of the QST battery of the DFNS and the intra-dermal capsaicin model.

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

Samenvatting

ID

NL-OMON27710

Bron
NTR

Verkorte titel
N/A

Aandoening

Neuropathic pain.

Ondersteuning

Primaire sponsor: Principal Investigator is Thijs Van Iersel
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Local tolerability of QST battery.

Toelichting onderzoek

Achtergrond van het onderzoek

The QST battery of the DFNS (Rolke 2006) is a comprehensive measurement for neurosensory function. The current study is a phase 0 study to assess the repeatability of the QST battery of the DFNS and the intra-dermal capsaicin model. This study is a two period study in 12 healthy subjects. After assessing eligibility during a 3-week screening period, each subject will participate during two separate study periods. Each period, the subjects will be subjected to QST testing according to the DFNS criteria. The first period, subjects will receive instructions regarding the DFNS QST battery before the actual testing proceeds. After the QST testing, subjects will receive a single dose of intra-dermal capsaicin in each period. Thereafter, capsaicin induced pain, the area of hyperalgesia and the area of flare will be assessed. There will be minimum of 3 days between the 2 periods.

Doel van het onderzoek

The QST battery of the DFNS (Rolke 2006) is a comprehensive measurement for neurosensory function. The current study is a phase 0 study to assess the repeatability of the QST battery of the DFNS and the intra-dermal capsaicin model.

Onderzoeksopzet

1. Cold Detection Threshold > Neurosensory analyzer (MEDOC);

2. Warm detection threshold > Neurosensory analyzer (MEDOC);

3. Thermal sensory Limen > Neurosensory analyzer (MEDOC)
Paradoxical heat sensations > Neurosensory analyzer (MEDOC);

4. Cold pain threshold > Neurosensory analyzer (MEDOC);

5. Heat pain threshold > Neurosensory analyzer (MEDOC);

6. Mechanical detection threshold > von Frey hairs (Optihair Set Marstock Nervtest

germany);

7. Mechanical Pain threshold > weighted pin prick stimulators;

8. Mechanical pain sensitivity > weighted pin prick stimulators;

9. Dynamic mechanical allodynia > a cotton wisp (force 3mN), a Q-tip mounted on a flexible plastic strip (force 100 mN) and a soft brush (force 400 mN);

10. Windup ratio > weighted pin prick stimulators;

11. Vibration threshold > Rydel Seiffer graded tuning fork (64 Hz, 8/8/ scale);

12. Pressure pain threshold > Pressure gauge device (FDN200, Wagner Instruments, US);

13. Area of hyperalgesia > 21.5 g von Frey hair;

14. Area of flare;

15. Primary hyperalgesia.
Capsaicin induced pain (VAS score)
Heart rate variability

Onderzoeksproduct en/of interventie

Challege agent capsaicine.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible subjects must meet all of the following inclusion criteria:

1. Signed Informed Consent prior to any study related procedure;

2. Healthy, fair skinned, Caucasian subjects;

3. Aged between 18 and 55, extremes included, at screening;

4. No active, significant, acute or chronic illness as determined by past medical history and physical examination at screening;

5. Ability to communicate well with the investigator, in the local language, and to understand and comply with the requirements of the study;

6. Sinus rhythm on 12-lead ECG.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Eligible subjects must meet none of the following exclusion criteria:

1. Test with an investigational drug within 3 months prior to the first dose;

2. Positive urine drug screen, alcohol breath test or pregnancy test (for females) at screening or day 1;

3. Known hypersensitivity to any of the contents of the study medication;

4. History or clinical evidence of any disease, and/or the existence of any surgical or medical condition, which might interfere with the study assessments such as diabetes, active or

recent (one year) herpes zoster, neurological disease, significant dermatosis of the forearm;

5. History of clinical significant cardiac disease including arrhythmia;

6. Clinically significant abnormal values for clinical chemistry, hematology or urinalysis at screening;

7. Clinically significant abnormal 12-lead ECG at screening;

8. Use of any medication, prescription or over-the-counter with an analgesic effect within 48 hours before the QST measurement or within 5 half-lives before the QST measurement, whichever is longer;

9. Legal incapacity or limited legal capacity at screening;

10. Any circumstances or conditions which, in the opinion of the investigator, may complicate or compromise the study, or the well being of the subject;

11. Employees of the investigator or study centre, as well as first grade family members of the employees or the investigator.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
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:	24-07-2009
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-07-2009
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	NL1814
NTR-old	NTR1924
CCMO	NL29002.056.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A