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

No registrations found.

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

Summary

ID

NL-OMON27710

Source
NTR

Brief title
N/A

Health condition

Neuropathic pain.

Sponsors and support

Primary sponsor: Principal Investigator is Thijs Van Iersel
Source(s) of monetary or material Support: Xendo Drug Development BV
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Intervention

Outcome measures

Primary outcome

Local tolerability of QST battery.

Secondary outcome

(Local) tolerability of intra-dermal capsaicin.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

Challege agent capsaicine.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-07-2009
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-07-2009

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1814
NTR-old	NTR1924
CCMO	NL29002.056.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A