Development of a nociceptive test battery - acute pain tests

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Primary Objective* Investigate the feasibility, applicability, safety, tolerability, and reproducibility of nociceptive tests in healthy volunteers.Secondary Objectives* Investigation of confounding factors including fear of pain, mood, age and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON34385

Source
ToetsingOnline

Brief title
Development of pain tests battery

Condition

- Peripheral neuropathies

Synonym
Pain

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: door de stichting CHDR zelf gefinancierd

Intervention

Keyword: nociception, Pain, Pain tests

Outcome measures

Primary outcome

Primary study endpoints

* Pain threshold and tolerance levels for each nociceptive test: pressure

pain (muscle) (kPa), electrical pain (skin) (mA), cold pressor pain (sec).

Secondary outcome

Secondary study endpoints

* Continuous VAS of pain intensity.

* McGill Pain Questionnaire Scores.

* STAI-DY1 scores.

Study description

Background summary

Pharmaceutical science continues to search for suitable biomarkers that can assist in predicting the therapeutic potential of analgesic medication and therefore, it*s efficacy in its target population. Data intensive, early-phase studies provide a valuable opportunity that can offer this translational information. A series of nociceptive pain tests early in drug development could be used to:
* bridge findings in the laboratory and those in the clinical situation,
* provide valuable information in regard to the mechanism of action of a new drug,
* predict most applicable patient population to be studied, and
* ascertain the most relevant nociceptive test for more intensive PK/PD modeling.

The need to use a comprehensive battery of pain models is highlighted by studies whereby only a single pain model, thought to relate to the clinical situation, demonstrates lack of efficacy. No single experimental model can

replicate the complex nature of clinical pain (1). Therefore, one experimental pain model cannot be used exclusively to screen the pharmacological action of a compound. Therefore, the objective of this protocol will be to integrate a range of tests such that they can be used as a combined screening tool for early drug development.

Study objective

Primary Objective
* Investigate the feasibility, applicability, safety, tolerability, and reproducibility of nociceptive tests in healthy volunteers.

Secondary Objectives
* Investigation of confounding factors including fear of pain, mood, age and subject sex.
* Explore logistics, practicalities, and potential refinement of techniques.
* Comparison to historical data, with particular reference to the impact that multiple nociceptive tests have on each other.
* Investigate two types of electrodes impact on electrical stimulation task endpoints.

Study design

This is a validation study and will consist of two study visits as outlined in the study schedule (see table 1), both starting at the same time of the day (± 2 hours). The schedule of the pain tests, in both frequency and duration, are representative of a typical exploratory study investigating an oral analgesic.

Being exploratory in nature no formal power analysis will be performed. However, to duplicate a typical early phase study, 20 subjects in total will be tested. Precision data will be used to determine sample sizes for future studies.

Study burden and risks

During and after the tests subjects can possibly feel pain and discomfort because of exposure to a few stimulations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subject:
* Agree to and be capable of signing an informed consent form.
* Healthy male and female subjects;
* Age: 18 to 65 years at screening (inclusive);
* Body mass index between 18-30 kg*m-2 (inclusive);
* Able to refrain from strenuous physical exercise from 48 hours prior to each nociceptive test until dismissal from the CHDR clinic;
* Able to refrain from alcohol use from 24 hours prior to and for the duration of every stay at the CHDR clinic;
* Ability to communicate well with the investigator in the Dutch language.
* Ability for female subjects to attend study days while in the follicular phase (3-13 days after onset of menstruation).

Exclusion criteria

* Legal incapacity or inability to understand or comply with the requirements of the study;
* 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 (paraesthesia, etc.);
* Pregnancy
* History or clinical evidence of alcoholism or drug abuse;
* Use of prescription, illicit or herbal medication within 7 days of nociceptive assessments;
* Use of over-the-counter medications within 3 days of nociceptive assessments.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL32572.058.10