

Quantitative sensory testing (QST) protocol.

Published: 23-03-2010

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To improve our insight in chronic pain and to develop methodologies to treat chronic pain.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34703

Source

ToetsingOnline

Brief title

QST procedure

Condition

- Other condition

Synonym

chronic pain, skin sensitivity

Health condition

chronische pijn (bij patienten)

Research involving

Human

Sponsors and support

Primary sponsor: PRA International EDS

Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: chronic pain, sensitivity affected skin

Outcome measures

Primary outcome

Criteria for evaluation

Assessments:

Detection thresholds and pain thresholds for thermal and mechanical stimulation, number of paradoxical heat sensations during the thermal sensory limen procedure, mechanical pain sensitivity, dynamic mechanical allodynia, temporal pain summation, vibration detection threshold, pressure pain threshold.

Statistical methods:

Z-scores will be calculated for each QST parameter.

Secondary outcome

n.a.

Study description

Background summary

PRA International and the Pain Center of the UMCG are collaborating in research on chronic pain. For this research, patients with chronic pain will undergo a series of tests that will determine the sensitivity of the affected skin and the underlying tissues of specific body parts. To be able to properly interpret the data, we also need comparable data from healthy subjects.

Study objective

To improve our insight in chronic pain and to develop methodologies to treat

chronic pain.

Study design

Design:

Open-label, open-end QST study.

Procedures and assessments

Assessments:

Medical history, cold and warm detection thresholds, number of paradoxical heat sensations during the thermal sensory limen procedure, cold and heat pain thresholds, mechanical detection threshold, mechanical pain threshold and mechanical pain sensitivity, dynamic mechanical allodynia, temporal pain summation, vibration detection threshold, and pressure pain threshold are tested in patients on the body part where they experience pain and, if this is possible, its (non painful) contralateral counterpart; if this is not possible, QST will be performed on the dorsal foot or hand, whichever is closest to the part in which pain is experienced; in healthy volunteers, QST will be performed on the dorsal foot and hand.

Intervention

No medication will be administered.

Study burden and risks

The investigation does not involve any risks.

Contacts

Public

PRA International EDS

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9471 GP Zuidlaren
NL

Scientific

PRA International EDS

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with chronic pain

Gender: male and female

Age: between 18 and 80 years of age, inclusive

Pathology: chronic pain history of 3 months or longer

pain has been considered by a physician to be either of neuropathic origin, or resulting from nerve damage due to diabetes mellitus, of postherpetic neuralgia, of phantom pain (i.e., pain resulting from an amputated limb)

Weight: no specific criteria; Healthy volunteers

Gender: male and female

Age: between 18 and 80 years of age, inclusive

Weight: no specific criteria

Exclusion criteria

Patients with chronic pain:

- mental handicap; Healthy volunteers:

- history of chronic pain
- history of neurological disorders
- history of psychiatric disorders
- regular use of pain medication

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-03-2010

Enrollment: 400

Type: Actual

Ethics review

Approved WMO

Date: 23-03-2010

Application type: First submission

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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

CCMO

ID

NL31914.056.10