Intra-subject variability in pain scoring and the consequences for analgesia treatment.

No registrations found.

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

Summary

ID

NL-OMON24774

Source
NTR

Brief title
Vapaana

Health condition

Acute and chronic pain
Pain relief
Analgesia

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Pain scores (NRS).

Secondary outcome

Variability in pain scores (NRS).

Study description

Background summary

Predicting the analgesic effect of pain medication is an important topic in chronic pain research, especially in the field of neuropathic pain. A recent finding of major interest was that the amount of pain relief produced by capsaicine patches could be predicted by the amount of variability of the pre-treatment spontaneous pain scores of the patients. Therefore, we want to further explore the predictability of pre-treatment pain variability on the probability to experience pain relief. To this end we will determine variability on experimentally induced heat and electrical pain stimuli to determine its predictive potential for opioid-induced analgesia (i.e. alfentanil). Furthermore, variability tests will be repeated after opioid administration to evaluate the effect of opioids on pain variability.

The aims of the study are:

1. To evaluate individual pain variability in the study groups;

2. To evaluate the predictive properties of pain variability on alfentanil analgesia;

3. To evaluate the effect of alfentanil on pain variability.

28-3-2014: Most important changes in the Vapaana protocol:
• Quantitative Sensory Testing (QST) and corneal confocal microscopy measurements were added to the protocol for fibromyalgia patients.
• A group of 40 obese patients (BMI > 35) was added to the patient groups in the protocol, and their measurements include QST as is done in the fibromyalgia group.
• Outcome measures are the QST data (as described by Rolke et al. 2006).

Study objective

Healthy volunteers and patients with a high variability in pain scores have a high probability to experience pain relief from alfentanil opposed to volunteers and patients with a low variability in pain scores.

Study design

Measurements by the VAS or NRS for pain. To measure variability 10 scores will be taken.

This will be done 2 times, under placebo and under alfentanil condition.

Intervention

Analgetic drug (alfentanil = 100ng/ml) infusion. Subjects will score thermal and electrical pain before and during alfentanil and placebo infusion (crossover design). We will assess whether the variability in pain scores prior to infusion can predict the amount of analgesia by alfentanil.

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Eligibility criteria

Inclusion criteria

Volunteer inclusion criteria:

1. Healthy subjects of either sex between the age of 18 and 75;

2. Being able to give written informed consent.

Patient inclusion criteria:

1. Patients diagnosed with fibromyalgia or peripheral polyneuropathy according to the guidelines of the IASP or other professional pain societies (e.g., Netherlands Society of Anesthesiologists); or patients scheduled for elective abdominal surgery with post-operative PCA or PCEA;

2. A pain score of 5 or higher for chronic pain patients;

3. Age between 18 and 75 years;

4. Being able to give written informed consent.

Exclusion criteria

Patient and volunteer exclusion criteria:

1. Unable to give written informed consent;

2. Medical disease such as pulmonary, renal, liver, cardiac, gastro-intestinal, vascular disease;

3. Allergy to study medication;

4. Use of strong opioids;

5. Use of benzodiazepines;

6. History of illicit drug abuse or alcohol abuse;

7. History of psychosis;

8. Epilepsy;

9. Raised intracranial pressure;

10. Pregnancy and/or lactation.

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2013
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-12-2012
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	NL3610

Register	ID
NTR-old	NTR3769
Other	LUMC : P12.252
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A