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

Gepubliceerd: 12-12-2012 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON24774

Bron
Nationaal Trial Register

Verkorte titel
Vapaana

Aandoening

Acute and chronic pain
Pain relief
Analgesia

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain scores (NRS).

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-01-2013
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-12-2012
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	NL3610
NTR-old	NTR3769
Ander register	LUMC : P12.252
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A