Influence of the new agent tapentadol on the perception of pain.

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1. Measure DNIC and offset analgesia in neuropathic pain patients; 2. Compare DNIC and offset analgesia in chronic pain patients with DNIC and offset analgesia in healthy volunteers; 3. Assess the effect of oral tapentadol on DNIC and offset...

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

Samenvatting

ID

NL-OMON20737

Bron
NTR

Verkorte titel
The TPT study

Aandoening

Chronic neuropathic pain patients

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Grunenthal GmbH, Aachen Germany

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Diffuse Noxious Inhibitory Control (DNIC);

2. Offset analgesia.

Toelichting onderzoek

Achtergrond van het onderzoek

Tapentadol is a centrally acting analgesic with two mechanisms of action: a μ-opioid receptor agonism and noradrenaline (NA) reuptake inhibition. Although the binding of tapentadol to the μ-opioid receptor is weaker than that of morphine its analgesic action is similar to that of morphine due to the (synergistic) effect of the second mechanism (i.e., NA reuptake inhibition). NA plays a role in the endogenous descending pain inhibitory system. Especially at descending pathways NA reuptake inhibition plays a crucial role at the spinal level to reduce chronic neuropathic pain. Hence it is to be expected that tapentadol has a modulatory role on DNIC and OA and consequently will ameliorate pain in chronic neuropathic pain patients.

12-10-2013: In this double-blind randomized controlled trial, 24 patients with neuropathic pain and diabetes (DPN) were randomized to receive either a 4 week treatment with oral tapentadol (max. 500 mg oral dose per day given in two doses) or placebo. The dose was titrated up in steps of 100 mg until side effects occurred. When side effects were unacceptable to the patient the dose could be reduced. Prior to dosing the DNIC response and offset analgesia response in these patients was measured. The same tests were repeated on the last day of dosing. Prior to dosing and during treatment pain intensity scores were obtained at 1 week intervals. Inclusion criteria, exclusion criteria, primary, secondary outcomes and summary are identical to the primary study.

Doel van het onderzoek

1. Measure DNIC and offset analgesia in neuropathic pain patients;

2. Compare DNIC and offset analgesia in chronic pain patients with DNIC and offset analgesia in healthy volunteers;

3. Assess the effect of oral tapentadol on DNIC and offset analgesia relative to placebo and morphine.

We hypothesize that neuropathic pain patients will have abberant endogenous pain modulatory responses that will restore on administering tapentadol.

Onderzoeksopzet

1. DNIC and offset analgesia will be measured 1 hour after administration of the treatments;

2. Spontaneous pain scores of the patient group will be evaluated 1, 3, 5 and 24 hours after intervention.

Onderzoeksproduct en/of interventie

Healthy volunteers and patients will be treated with tapentadol 100mg, morphine 40mg and a placebo on separate occasions. The influence of these treatments on the endogenous control pain will be evaluated.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients diagnosed with small-fiber neuropathy or according to the guidelines of the IASP or other professional pain societies (eg. Netherlands Society of Anesthesiologists);

2. A pain score of 5 or higher;

3. Age between 18 and 75 years;

4. Being able to give written informed consent.

Volunteer inclusion criteria. Healthy volunteers in the age range 18-75 years of either sex.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Unable to give written informed consent;

2. Medical disease such as pulmonary, renal, liver, cardiac, gastro-intestinal, vascular (incl. hypertension) 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:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	24
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:	26-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34371
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2589
NTR-old	NTR2716
CCMO	NL34186.058.10

Register	ID
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34371

Resultaten

Samenvatting resultaten
N/A