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

No registrations found.

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

Summary

ID

NL-OMON20737

Source
NTR

Brief title
The TPT study

Health condition

Chronic neuropathic pain patients

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Grunenthal GmbH, Aachen Germany

Intervention

Outcome measures

Primary outcome

1. Diffuse Noxious Inhibitory Control (DNIC);

2. Offset analgesia.

Secondary outcome

1. Spontaneous pain scores of the patients.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-01-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34371
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2589
NTR-old	NTR2716
CCMO	NL34186.058.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34371

Study results

Summary results
N/A