The effect of ketamine on inhibitory pain mechanimsm in the central nervous system in chronic pain patients.

No registrations found.

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

Summary

ID

NL-OMON28485

Source
NTR

Brief title
DNIC and offset analgesia study

Health condition

Complex Regional Pain Syndrome type 1, fibromyalgia and neuropathic pain patients.

Sponsors and support

Primary sponsor: This study is part of TREND (Trauma RElated Neuronal Dysfunction).
Source(s) of monetary or material Support: This study is part of TREND (Trauma RElated Neuronal Dysfunction).

Intervention

Outcome measures

Primary outcome

1. Presence of DNIC;

2. Presence of offset analgesia;

3. Effect of ketamine on DNIC and offset analgesia.

Secondary outcome

Adverse events.

Study description

Background summary

The last years research on pain perception has been focusing on central pain modulatory systems like Diffuse Noxious Inhibitory Control (DNIC) and offset analgesia. Dysfunction of DNIC is associated with chronic pain diseases like irritable bowel syndrome and fibromyalgia. Furthermore, accumulating evidence is available about the involvement of the N-methyl-D-aspartate receptor (NMDAR) on chronic pain states. It has recently been shown that the NMDAR-antagonist ketamine can accomplish long-lasting pain relief in patients diagnosed with Complex Regional Pain Syndrome Type-1 (CRPS-1). This study will focus on DNIC and offset analgesia in patients diagnosed with CRPS-1, small-fibre neuropathy and fibromyalgia, compared to healthy controls. The effect of ketamine on pain relief as well as on DNIC and offset analgesia will be investigated.

A total of 60 subjects will be tested for DNIC and offset analgesia. The DNIC experiment is performed by applying a noxious, thermal heat stimulus to the forearm with simultaneous immersion of the subjects foot in cold water. During the test, the subjects records real time pain scores with an Electronically Visual Analogue Scale (eVAS). Offset analgesia is tested by giving a noxious thermal stimulus which is increased with 1°C for 5 sec. Again the subject will real time score the amount of pain using the eVAS. Both experiments will be performed before and after infusion with low-dose (S+)-ketamine.

The main end-point of this study is the effect of ketamine on eVAS, which will be evaluated in a within group comparison using a paired t-test. A separate analysis will be done evaluating the effect of ketamine on DNIC and offset analgesia. For the between group comparison an analysis of variance will be performed comparing the patient groups to the age- and sex matched control group.

Study objective

In this study it is hypothesised that the inhibitory pain mechanisms DNIC and offset analgesia are affected in chronic pain patients compared to healthy controls. Furthermore it is hypothesised that ketamine has a improving effect on these pain mechanisms.

Study design

One trial takes 6 hours. Subjects need to come only ones.

Intervention

The administration of intravenous S(+)-ketamine.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients diagnosed with CRPS-1, small-fiber neuropathy of fibromyalgia, according to the guidelines of the IASP or other professional pain societies;

2. A pain score of 5 or higher;

3. Age between 18 and 75 years;

4. Being able to give written informed consent.

Exclusion criteria

1. Unable to give written informed consent;

2. Medical disease such as renal, liver, cardiac, vascular (incl. hypertension) or infectious disease;

3. Increased intracranial pressure;

4. Epilepsy;

5. Psychosis;

6. Glaucoma;

7. A history of cerebro-vascular accident < 1 year;

8. Pregnancy;

9. Obesity (BMI>30).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-01-2009

Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion Date:	10-09-2009
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	NL1891
NTR-old	NTR2005
Other	METC LUMC : P09.107
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A