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

Gepubliceerd: 10-09-2009 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON28485

Bron
NTR

Verkorte titel
DNIC and offset analgesia study

Aandoening

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

Ondersteuning

Primaire sponsor: This study is part of TREND (Trauma RElated Neuronal Dysfunction).
Overige ondersteuning: This study is part of TREND (Trauma RElated Neuronal Dysfunction).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Presence of DNIC;
2. Presence of offset analgesia;
3. Effect of ketamine on DNIC and offset analgesia.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

The administration of intravenous S(+)-ketamine.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-01-2009
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-09-2009
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	NL1891
NTR-old	NTR2005
Ander register	METC LUMC : P09.107
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A