Investigating the sensitivity of the central nervous system in patients with chronic low back pain radiating to the leg

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To determine the presence or absence of central sensitisation in patients with Chronic Low Back Pain with radiation to the leg (CLBPr) and to determine the effect of segmental nerve interventions on central sensitisation.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24108

Bron
NTR

Verkorte titel
CLASSICO

Aandoening

chronic low back pain, central sensitisation, segmental nerve root block, pulsed radiofrequency; chronische lage rugpijn, centrale sensitisatie, segmentale zenuwwortel blokkade, radiofrequentie zenuwwortel behandeling

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Quantitative Sensory Testing (QST; T1,T1a,T1b,T2,T3)
2. Bedside Examination (BSE; T1,T1a,T1b,T2,T3)
3. Central Sensitization Inventory (CSI; T1,T1a,T1b,T2,T3)

Toelichting onderzoek

Achtergrond van het onderzoek

There is growing evidence for sensitisation in patients with chronic pain. Continuing nociceptive inputs can induce a reduction in threshold and an increase in responsiveness of peripheral nociceptors, i.e. peripheral sensitisation, which on itself may lead to a prolonged increase in excitability and synaptic efficacy of neurons in central nociceptive pathways, i.e. central sensitisation. Several methods are advocated to measure central sensitisation. For example, quantitative sensory testing (QST) is a psychophysical method that objectively measures responses to calibrated graded innocuous or noxious stimuli and represents, in most respects, an extension of the routine standardised sensory measurements. Furthermore, central sensitisation can be assessed with the Central Sensitisation Inventory (CSI). For treatment of severe cases of chronic low back pain, patients are referred to multidisciplinary pain clinics for further assessment. If the diagnosis in patients with chronic low back pain radiating to the leg (CLBPr) is not clear despite extensive physical, neurological, orthopaedic and radiological examination, a precision diagnosis, such as diagnostic segmental nerve root block (dSNRB), has been advocated. After a positive dSNRB, possible interventions are therapeutic SNRB (tSNRB) or pulsed radiofrequency (pRF). The extent of central sensitisation in patients with CLBPr, its role in chronification and its interaction with diagnostic and therapeutical interventions are unknown up to now.

Therefore, the main questions of this study are: can we find signs of central sensitisation in patients with CLBPr? Can we quantify it? Do the interventions (tSNRB and pRF) normally applied in care as usual affect central sensitisation?

Doel van het onderzoek

To determine the presence or absence of central sensitisation in patients with Chronic Low Back Pain with radiation to the leg (CLBPr) and to determine the effect of segmental nerve interventions on central sensitisation.

Onderzoeksopzet

T1=measurements before diagnostic SNRB

T1a = optional measure 1 week after first diagnostic SNRB, measure before second diagnostic SNRB
T1b = optional measure 1 week after second diagnostic SNRB, measure before third diagnostic SNRB
T2=measurements 1 week after diagnostic SNRB, just before segmental nerve intervention

T3=measurement 4 weeks after segmental nerve intervention

Onderzoeksproduct en/of interventie

This study will include 50 patients and 50 age and gender matched controls.

Patients will receive care as usual. Segmental nerve intervention will be performed according to the standard procedures of the Anesthesiology Pain Center of the University Medical Center of Groningen:

dSNRB (diagnostic Sensory Nerve Root Block):

- Bupivacaine 0,75% 0,3ml with Visipaque 320 mg I/ml 0,3ml (total 0,6ml). Inject 0,35 – 0,55 ml in total

tSNRB (therapeutic Sensory Nerve Root Block):

-L3 and lower: Bupivacaine 7,5mg + Triamcinolon 40mg + Visipaque 320 mg I/ml together in one 5 ml syringe.

L2 and higher: Bupivacaine 7,5mg + Dexamethason 5mg + Visipaque 320 mg I/ml together in one 5 ml syringe.

pRF (pulsed RadioFrequency):

pulsed radiofrequency (20msec on, 480msec off)

on 45V during 4 min, temp <42 degrees Celcius

Pain and Quality of Life parameters will be collected to assess and quantify central sensitisation during several stages of the care as usual procedure.

Healthy control subjects will not receive any segmental nerve intervention, but will perform all other measurements on given timepoints.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Presence of CLBP radiating to the leg;

- Leg pain >= back pain;

- Physician must consider therapeutic Sensory Nerve Root Blocking (SNRB) or pulsed RadioFrequency (pRF) as an appropriate treatment intervention;

- Age: 18-65 years old;

- Agreement and signature of the informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Exclusion criteria for segmental nerve blocks (according to local protocol)

- No or not sufficient understanding of Dutch language;

- Incapacity to follow instructions;

- Mental incompetence to provide informed consent;

- CLBP with radiation to both legs;

- Pain in one (or more) sites where BSE and QST will be applied (except for the most painful point in the painful dermatome).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
The de-identified individual clinical trial participant-level data (IPD) will be shared. All individual participant data that underlie the results reported in this article will be shared after de-identification (text, tables, figures, and appendices). The study protocol will also be available. The data will be available beginning nine months following article publication and for a maximum period of 15 years. To make the data findable and accessible for others, we will include a description of the UMCG data catalogue data: https://www.groningendatacatalogus.nl/. Researchers who provide a methodologically sound proposal can access the data with a signed data access agreement.

Ethische beoordeling

Positief advies

Datum:	10-01-2018
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	NL6765
NTR-old	NTR6942
Ander register	METc Univeristy Medical Center Groningen : METc 2017/420

Resultaten