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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24108

Source
NTR

Brief title
CLASSICO

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

1.36-Item Short Form Health Survey (SF-36; T1,T3)

2.Pain Disability Index (PDI; T1,T3)

3.Work Ability Index (WAI; T1,T3)

4.STarT Back Screening Tool (SBST; T1,T3)

5.Numeric Rating Scale for Pain(VAS; T1,T1a,T1b,T2,T3)

6.Drawing in standard leg images (DPA; T1,T3)
7.Pain Catastrophising Scale (PCS; T1, T3)
8.Pain Vigilance and Awareness Questionnaire (PVAQ; T1,T3)

Study description

Background summary

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?

Study objective

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.

Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2018
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	10-01-2018
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	NL6765
NTR-old	NTR6942
Other	METc Univeristy Medical Center Groningen : METc 2017/420

Study results