LumbarPRF

Gepubliceerd: 07-04-2021 Laatst bijgewerkt: 18-08-2022

To identify the degree of variability in performing PRF procedures in patients with LRP, between different hospitals in the Netherlands and relate it to the efficacy of the procedure

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

Samenvatting

ID

NL-OMON25497

Bron
NTR

Verkorte titel
LPRF

Aandoening

Chronic neuropathic radicular pain

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC, Department of Anesthesiology
Overige ondersteuning: None, Investigator initiated study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the technical differences and the influence of single versus multiple lumbar levels in performing PRF treatment of lumbar radicular pain.

Toelichting onderzoek

Achtergrond van het onderzoek

Moderate evidence for treating lumbar radicular pain using PRF treatment is available. However PRF procedural settings such as voltage, number of cycles, treatment duration, and needle tip placement vary among pain physicians. Consequentially resistance (Ohm) and current (mA) can vary as well. Therefore is it not clear which treatment strategy contributes most substantial to pain reducing results.
The aim of the present prospective longitudinal observational data collection is twofold. First, the data collection should identify the degree of variability in performing PRF procedures in patients with LRP, between different hospitals in the Netherlands. Secondly, this data collection should identify differences in efficacy in pain reduction after 3 and 6 months, related to the different PRF treatment settings and needle tip positions.
These findings may help to obtain consensus on optimal PRF treatment duration, efficacy of single level versus multi level PRF, needle tip position, and length of active needle tip in order to obtain optimal pain reduction in patients with LRP. These data will serve as basis for new hypotheses regarding optimal PRF techniques to be tested in future RCT’s.

Doel van het onderzoek

To identify the degree of variability in performing PRF procedures in patients with LRP, between different hospitals in the Netherlands and relate it to the efficacy of the procedure

Onderzoeksopzet

Baseline: questionnaires and procedural variables
3 months: questionnaires and procedural variables
6 months: questionnaires and procedural variables

Onderzoeksproduct en/of interventie

Lumbar PRF procedure at baseline

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients >= 18 and <70 years
• Dutch speaking
• Dominant unilateral leg pain, with a back/leg pain ratio of at least 40/60%
• The leg pain should be the primary complaint with an average pain score of at least 5 on an 11-point numerical rating scale (NRS)
• Chronic LRP lasting >=6 months
• Previous inadequate conservative management such as physiotherapy, exercise therapy or analgesic (anti-neuropathic) medications
• Willing and able to sign consent for re-use of care data

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Refusal to participate in the data collection
• Age < 18 or >70 years
• Acute pain of onset lasting <12 weeks
• Radicular pain in both legs
• Signs of progressive motor weakness or neurologic deficits
• Planned lumbar and/or sacral surgery
• Patients who received epidural steroid injection(s) within the previous 6 months
• Patients who received previous PRF treatment within the previous 6 months
• Systemic infection
• Injection site infection
• Hypersensitivity to LA and/or the radiographic contrast agent
• Malignancy/presence of cancer as a cause of radicular pain
• Presence of a cardiac pacemaker
• Unstable medical or psychiatric condition
• Other current pain syndromes besides lumbar radicular pain
• Inability to receive a 6 months follow up

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-04-2021
Aantal proefpersonen:	700
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-04-2021
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	NL9396
Ander register	METC of Amsterdam UMC, location AMC : W21_019 # 21.021

Resultaten