LumbarPRF

No registrations found.

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

Summary

ID

NL-OMON25497

Source
NTR

Brief title
LPRF

Health condition

Chronic neuropathic radicular pain

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Department of Anesthesiology
Source(s) of monetary or material Support: None, Investigator initiated study

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To relate the abovementioned variables to patient clinical outcomes such as effective pain reduction.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Lumbar PRF procedure at baseline

Contacts

Public
Amsterdam Universiteits Medisch Centrum. locatie AMC

Jennifer Breel

0610019257
Scientific
Amsterdam Universiteits Medisch Centrum. locatie AMC
Jennifer Breel

0610019257

Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2021
Enrollment:	700
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-04-2021
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	NL9396
Other	METC of Amsterdam UMC, location AMC : W21_019 # 21.021

Study results