Pulsed radiofrequency for hand osteoarthritis pain

Published: 18-02-2022 Last updated: 27-12-2024

To assess the efficacy of transcutaneous pulsed radiofrequency therapy (tPRF) as a treatment

for pain in hand OA.

Ethical reviewApproved WMOStatusRecruitingHealth condition typeJoint disordersStudy typeInterventional

Summary

ID

NL-OMON51929

Source

ToetsingOnline

Brief title

PROAP

Condition

· Joint disorders

Synonym

Hand osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ReumaNederland

Intervention

Keyword: Hand osteoarthritis, Pain, Pulsed radiofrequency, Sensitization

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Outcome measures

Primary outcome

Hand pain assessed with the numerical rating scale over 6 weeks after treatment compared to sham.

Secondary outcome

Associations of somatosensory profiles measured with quantitative sensory testing and transcutaneous pulsed radiofrequency therapy efficacy.

Efficacy of pulsed radiofrequency therapy efficacy in hand osteoarthritis measured in depression and anxiety scores, hand function, global perceived effect, health-related quality of life.

Study description

Background summary

Different types of pain may be present in patients with hand osteoarthritis (OA), including nociceptive pain and non-nociceptive pain. This makes adequate pain treatment difficult, and thus new treatment options are needed.

Study objective

To assess the efficacy of transcutaneous pulsed radiofrequency therapy (tPRF) as a treatment for pain in hand OA.

Study design

Randomized clinical trial (RCT).

Intervention

Transcutaneous pulsed radiofrequency therapy of the hand versus sham.

Study burden and risks

This RCT will have little burdens and risk for the subjects. The proposed intervention, tPRF, is well tolerated, with no known serious side effects.

Contacts

Public

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Albinusdreef 2 Leiden 2333ZA NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Previous participation in and completion of the SensOA study

Exclusion criteria

Exclusion from the SensOA study

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Double blinded (masking used)

Control: Placebo

Primary purpose: Treatment

Recruitment

 NL

Recruitment status: Recruiting

Start date (anticipated): 12-05-2022

Enrollment: 60

Type: Actual

Medical products/devices used

Generic name: Pulsed radiofrequency generator

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 18-02-2022

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 18-07-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 08-12-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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

CCMO NL78447.058.21