Meralgia Paresthetica, locating the lateral femoral cutaneous nerve (LFCN) with elektro-stimulation followed by a therapeutic injection of methylprednisolone/lidocaïne (M/L), a double-blind randomized placebo-controlled clinical trial

Published: 30-06-2015
Last updated: 14-04-2024

The aim of this study is to analyse the analgetic effect of a local injection in the lateral femoral cutaneous nerve (LFCN) with methylprednisolone/lidocaine (M/L) after localisation through elektro stimulation VS placebo. In this trial we hope to…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON44713

Source
ToetsingOnline

Brief title
Meralgia Paresthetica Elektrostimulation Study

Condition

- Peripheral neuropathies

Synonym
Sensory entrapment neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: kosten worden gedragen door het ziekenhuis

Intervention

Keyword: Elektrostimulation, Meralgia paresthetica, Methylprednisolone/lidocaïne

Outcome measures

Primary outcome

Primary endpoint will be reduction of the pain score on a visual analogue scale

(VAS).

Secondary outcome

Secondary endpoints are:

- Pain reduction after injection measured on a different scale (pain worsening,

no improvement of pain, slight to moderate improvement of pain, complete

remission of pain.)

- Duration of pain reduction

- Reduction of oral analgetics (descriptive)

Study description

Background summary

Meralgia paresthetica (MP) is a mononeuropathy of the lateral femoral cutaneous nerve (LFCN) characterized by pain, numbness and tingling in the anterolateral aspect of the thigh. It can be organized as an entrapment neuropathy with a long list of differential diagnosis. Frequently its cause is spontaneous which include mechanical factors such as obesity, wearing a tight belt and

other conditions associated with increased intra-abdominal pressure (1). The incidence of meralgia paresthetica in the Rotterdam area is 4.3 per 10.000 a year. (2). In a previous study five different types of anatomical variation were described.(3) For interventional treatment of meralgia paresthetica such as local injections with anesthetics and corticosteroids the evidence is limited but seems beneficial however it has previously been performed in a blind fashion using an anatomical landmark. Locating a nerve with electrostimulation is easily applicable and usually well tolerated by patients. It does not require a radiologist or neurologist specialized in ultrasound.(4) This therapy can be used for a more accurate localization and a more accurate blockade of the LFCN.*

Study objective

The aim of this study is to analyse the analgetic effect of a local injection in the lateral femoral cutaneous nerve (LFCN) with methylprednisolone/lidocaine (M/L) after localisation through elektro stimulation VS placebo. In this trial we hope to objectify:
Therapeutic value of a localized injection with M/L in MP patients, when localized by elektro-stimulation.

Study design

This will be a single centered double-blind randomized placebo-controlled intervention study.

Intervention

Patients will be injected with 2,5 ml methylprednisolone/lidocaine or 2,5 ml saline 0,9% 1 cm medial of the anterior superior iliac spine after localisation with electro stimulation of the LFCN.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Needle examination is a study that is often used for the treatment of MP and does not form an additional risk for the patient group. Often described adverse effects for both groups are haematoma, reversible dermatomal change or duration of pain after injection. Furthermore a temporary increase in numbness in the area of the LFCN can occur.

Contacts

Public
HagaZiekenhuis

Leyweg 275
Den haag 2545CH
NL
Scientific
HagaZiekenhuis

Leyweg 275
Den haag 2545CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients with newly diagnosed idiopathic meralgia paresthetica will be recruited. Age: 18 years and older. Duration 4 weeks or more.
Diagnostic criteria: Meralgia paresthetica characterized by pain, numbness and tingling in the anterolateral aspect of the thigh in the area of the LFCN

Exclusion criteria

1. Coexisting disorders or conditions that may mimic MP such as lumbar radiculopathy, severe polyneuropathy.
2. Known allergic reaction to methylprednisolone/lidocaine.
3. Pregnancy

4. No localization possible through electrostimulation
5. Systemic viral or fungal infections
6. Known allergy to steroids
7. No injection with steroids can be given in a vicinity of a preexistent infectious area

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-medrol/ lidocaine
Generic name:	Depo-medrol/ lidocaine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	02-06-2017
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
EudraCT	EUCTR2014-004052-54-NL
CCMO	NL50504.098.15

Study results

Results posted:	10-08-2018
Actual enrolment:	20

First publication
31-05-2018