Effectiveness of neurolysis versus neurectomy of the lateral femoral cutaneous nerve (LFCN) in the treatment of meralgia paresthetica.

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

Summary

ID

NL-OMON56394

Source
ToetsingOnline

Brief title
Surgical Treatment Options for Meralgia Paresthetica (STOMP).

Condition

- Peripheral neuropathies
- Nervous system, skull and spine therapeutic procedures

Synonym
burning and tingling on the front and side of the thigh, meralgia paresthetica

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: wetenschapsbureau van het MC Haaglanden

Intervention

Keyword: cutaneous nerve, femoris, neuropathy

Outcome measures

Primary outcome

Likert scale for self-perceived recovery.

Secondary outcome

VAS, Bothersomeness index for pain and numbness.

Study description

Background summary

Despite conservative therapy with pain medication, meralgia paresthetica persists in about 10% of the patients. These patients are candidates for surgical therapy. There are two surgical option: neurolysis and neurectomy. During the neurolysis procedure the nerve is released at the site where it runs through the inguinal ligament of Poupart. This results in pain relief in about 60% of the cases. During the neurectomy procedure the nerve is transected proximal to the ligament. The latter procedure results in pain relief in about 90% of the cases, but obviously disadvantage of this procedure is a postoperative area of numbness in the thigh. We found in a recent retrospective study that most patients are not bothered by this 1. Disadvantage of this study however was that it was based on two historical cohorts and that patients were not blinded for the procedure. Currently, there is no randomized study in the literature on this subject.

Study objective

The goal of the stomp trial will be to investigate the effectiveness of both the neurolysis and neurectomy procedure in patients with persistent symptoms of meralgia paresthetica. In addition, in this trial we want to determine to what extend patients are bothered by the numbness following the neurectomy

procedure. For the latter we will use the Sciatica Bothersomeness Index.

Study design

Patients with persistent symptoms of meralgia paresthetica (despite at least 3 months of conservative therapy) will be randomized for two surgical treatments. After the surgery patients will be followed for 1 year.

Intervention

Neurolysis versus neurectomy

Study burden and risks

Besides the standard visits to the outpatient clinic after 6 weeks, patient will receive a call after 12, 26 and 52 weken. There is no other burden, and there are no risks for the patient.

Contacts

Public
Haaglanden Medisch Centrum

Lijnbaan 32
Den Haag 2512VA
NL
Scientific
Haaglanden Medisch Centrum

Lijnbaan 32
Den Haag 2512VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* diagnosis of resistant idiopathic meralgia paresthetica.
* age 18-80 years
* ability and willingness to comply with project requirements
* written informed consent

Exclusion criteria

* Previous surgery for meralgia paresthetica
* Nerve root compression on MRI of the lumbar spine
* Intra-abdominal lesion or previous abdominal surgery, including qynecologic surgery, surgery for inguinal herniation, hip surgery
* Other previous trauma to the inguinal area, which may have caused symptoms of meralgia paresthetica, including fe seat-belt injury
* Severe mental or psychiatric disorder
* Inadequate Dutch or English language
* Planned (e)migration abroad in the year after inclusion

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2014

Enrollment:	67
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	19-06-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	09-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	18-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	02-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	28-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-10-2023
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	NL46074.098.13