

Meralgia paresthetica

a study of diagnosis, prognosis and treatment

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A. What are possible causes of MP and what patients variable are associated with MP. What is the natural course and prognosis of MP. What is the influence of MP on the quality of life. B. What is the diagnostic value of SSEP en nerve conduction...

Ethical review	Approved WMO
Status	Pending
Health condition type	Peripheral neuropathies
Study type	Observational invasive

Summary

ID

NL-OMON30771

Source

ToetsingOnline

Brief title

Meralgia paresthetica

Condition

- Peripheral neuropathies

Synonym

nervus cutaneus femoralis lateralis compression, pain or an irritating sensation on the outer side of the thigh

Research involving

Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis

Source(s) of monetary or material Support: Canisius Wilhelmina Ziekenhuis

Intervention

Keyword: diagnosis, meralgia paresthetica, prognosis, treatment

Outcome measures

Primary outcome

Diagnostic value of SSEP and nerve conduction studies expressed in positive- and negative predictive value.

Improvement of symptoms (pain, paresthesias, and hyperesthesia) in patients with MP 12 weeks after injection with corticosteroids. The pain, numbness and paresthesias are scored using a visual analog scale. Patients are also asked whether symptoms have improved, if they have no or only minor symptoms that they considered so much improved that they felt no further treatment is necessary.

Secondary outcome

Clinical improvement 6 months after treatment. Improvement in quality of life.

Study description

Background summary

Meralgia paresthetica (MP) is a relatively common entrapment neuropathy. Although this disorder has been known for over 100 years many questions remain as to the cause, prognosis and treatment of MP and what the role of clinical neurophysiology is.

Study objective

A. What are possible causes of MP and what patient variables are associated with MP. What is the natural course and prognosis of MP. What is the influence of MP on the quality of life.

- B. What is the diagnostic value of SSEP en nerve conduction studies.
- C. What is the diagnostic value of high resolution ultrasound studies.
- D. Does an injection with corticosteroids relieve the symptoms of MP.

Study design

Multicentre randomized dubbelblind trial. Patients with the diagnosis MP and case-controls are included in 3 centres. They are requested to fill in a questionnaire. A SSEP and nerve conduction studies will be performed. To exclude root disease needle exam will be done. Patients with MP will be given an injection with corticosteroids or placebo just next to the nerve where is passes under the inguinal ligament. The effect of the injection will be evaluated after 1, 3 and 6 months.

Study burden and risks

A SSEP, nerve conduction studies and needle examination are performed. These are studies routinely used in the evaluation of MP and do not pose any additional risks for participants. An injection with corticosteroids can result in an adverse reaction to the medication, only minor risks are associated with this procedure.

Contacts

Public

Canisius Wilhelmina Ziekenhuis

joulestraat 44
6533DG
Nederland

Scientific

Canisius Wilhelmina Ziekenhuis

joulestraat 44
6533DG
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patient with meralgia paresthetica. The diagnosis is made on clinical grounds, which is an abnormal sensation (pain, numbness, paresthesia, hyperesthesia) on the lateral side of the thigh.

Controls

Patients with a cervical radiculopathy or radiculopathy L4-L5-S1.

Exclusion criteria

Area of abnormal sensation extending beyond 2cm of the medial axis of the thigh or patella, previous operation for MP, diabetes, clinical symptoms and/or signs of a radiculopathy L2-3-4 or polyneuropathy.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	125

Type: Anticipated

Medical products/devices used

Product type: Medicine
Brand name: depo-medrol
Generic name: corticosteroids
Registration: Yes - NL intended use

Ethics review

Approved WMO
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2006-006381-42-NL
CCMO	NL14117.091.06