

Comparison of effectiveness of different surgical treatments for meralgia paresthetica

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We hypothesise a difference in outcome on pain relief in favour of the neurectomy group.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24522

Bron

NTR

Verkorte titel

STOMP

Aandoening

meralgia paresthetica, chirurgische behandeling, neurolyse, neurectomie

Ondersteuning

Primaire sponsor: Medical Center Haaglanden

Overige ondersteuning: Medical Center Haaglanden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Good outcome Likert scale (1/2)

Toelichting onderzoek

Achtergrond van het onderzoek

Meralgia paresthetica (MP) is a tingling, stinging or burning sensation in the anterolateral part of the thigh. It is often accompanied by varying degrees of numbness. Meralgia paresthetica is caused by a mononeuropathy of the lateral femoral cutaneous nerve (LFCN). It is commonly idiopathic, but can also have a traumatic origin, like seat belt and iatrogenic injury [1]. Usually symptoms are mild and resolve spontaneously. However, it may be severe and limit the patient in daily activities. Extension of the hip, as for example while walking or when driving a car, often exacerbates symptoms. Temporary nerve block with local anesthetic near the anterior superior iliac spine (ASIS) may relieve the symptoms and is often used to confirm the diagnosis [2]. MP is the most frequent mononeuropathy of the lower limb and probably more common than recognized [3, 4]. It is often misdiagnosed, especially in children/adolescents [5]. The pure sensory symptoms in MP can be helpful in the differential diagnosis with lumbosacral radiculopathy and orthopedic conditions. Electrophysiology and nerve block can support the diagnosis [6].

The initial treatment of MP is wait and see supported by conservative measures such as avoiding wear of tightly fitting cloths, analgetics and loss of weight by obese patients. It is reported to be successful in pain relief in about 90% of the cases [2]. If conservative treatment fails surgical treatment should be considered. The two main surgical options are neurolysis and neurectomy. In general, success rates are higher for the neurectomy procedure [7], but an obvious disadvantage is loss of sensation in the anterolateral part of the thigh. We recently reported our results for both procedures from two historical cohorts [8]. This study confirmed superior results reported in the literature for the neurectomy procedure (87.5% pain relief versus 60% after the neurolysis procedure). In addition, most patients noted not to be bothered by the numbness following the neurectomy procedure. Shortcomings of this study however are that it was conducted retrospective for two historical cohorts and that patients were not blinded for the procedure. No randomized study has been performed comparing both procedures [7]. Reason for this probably is the small number of patients that require surgery because of persistent symptoms of meralgia paresthetica. Therefore, a randomized trial can only be performed if multiple centres specialized in this type of surgery participate.

In this study protocol we will randomly and blindly compare both surgical procedures (neurolysis versus neurectomy) in patients with persistent symptoms of idiopathic meralgia paresthetica despite conservative treatment. We hypothesise a difference in outcome on pain relief in favour of the neurectomy group. Primary outcome measure will be the 7-point Likert scale (to determine perceived recovery). Secondary outcome measures will include VAS pain and Bothersomeness Index (to determine how much patients are bothered by the numbness following the neurectomy procedure) [9].

Doel van het onderzoek

We hypothesise a difference in outcome on pain relief in favour of the neurectomy group.

Onderzoeksopzet

6, 12, 26, 52 weeks

Onderzoeksproduct en/of interventie

Neurolysis vs neurectomy

Contactpersonen

Publiek

Neurochirurgie
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The Netherlands

Wetenschappelijk

Neurochirurgie
MC Haaglanden
Ziekenhuis Bronovo
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18-65 years
- Diagnosis of resistant idiopathic meralgia paresthetica, which must include:

- o Symptoms of a burning or tingling sensation in the anterolateral part of one or two thighs
- o At least 3 months of conservative treatment consisting of weight reduction (in case of overweight), avoiding wear of tight cloths, reducing repetitive motion (for example cycling), pain medication and local injection of corticosteroids
- o One or more positive nerve block(s) (local infiltration with lidocaine) and/or abnormal SSEP or delayed conduction time LFCN
- Ability and willingness to comply with project requirements
- Written informed consent given by the subject

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous surgery for meralgia paresthetica
- Nerve root compression on MRI of the lumbar spine
- Intra-abdominal lesion or previous abdominal surgery, including gynecologic surgery, surgery for inguinal herniation, hip surgery
- No 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-04-2014
Aantal proefpersonen: 90
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 20-04-2014
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4332
NTR-old	NTR4530
Ander register	METC : 13-073

Resultaten