Peripheral nerve decompression surgery as treatment of secondary headache caused by entrapment neuropathy of extracranial sensory nerves

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To evaluate the effect of peripheral nerve decompression surgery in patients with headache caused by entrapment neuropathy,comparing it to conventional treatment.

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

Summary

ID

NL-OMON49524

Source
ToetsingOnline

Brief title
Surgical treatment of headache caused by extracranial entrapment neuropathy

Condition

- Peripheral neuropathies

Synonym
headache to nerve compression, Neuralgia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Extracranial, Headache, Nerve compression, Surgery

Outcome measures

Primary outcome

Pain score: average daily headache intensity

o Measurement of headache intensity on a 10 point VAS.

o Measure daily in a diary

o Clinically relevant decrease defined as 50% or more

Secondary outcome

- Frequency of headache, defined as the number of days with headache per 28 days

- Frequency of serious headache, defined as the number of days with headache

per 28 days with a VAS of 5 or higher

- Change in frequency of days with acute headache medication use per 28 days

- Change in frequency of days with prophylactic medication use per 28 days

- Change in frequency of days with analgesic medication use per 28 days

- Loss of work.

- CEQ

- HIT-6

- SF-36

Study description

Background summary

Surgical decompression of peripheral sensory nerves seems to be an effective
way of treating headaches in patients with

diagnostically confirmed entrapment neuropathy. This is mostly based on prospective cohort studies. Well-designed randomised controlled trials to prove the effect of surgery compared to standard treatment or available non-surgical options are limited.

Study objective

To evaluate the effect of peripheral nerve decompression surgery in patients with headache caused by entrapment neuropathy, comparing it to conventional treatment.

Study design

Randomised controlled trial, with a follow up using a daily diary for one year and questionnaires at three months, one year and five years.

Intervention

Diagnostic nerve block at the site of local pain to confirm entrapment neuropathy. If successful the subject is randomised between surgical decompression or the standard medical treatment by the neurologist.

Study burden and risks

The burden consists of a maximum of seven visits to the outpatient clinic, three undergoing physical examination, one with diagnostic imaging modalities (resulting in low dose radiation from a CT scan) and one where a diagnostic nerve block is performed. A daily headache diary is kept (a frequently used tool by neurologists) and two questionnaires that are filled out three times during the study. There are no major adverse events described of surgical decompression in the head and neck area. Minor adverse events include itching, numbness, hyper- or hyposensitivity and operative-site specific adverse events such as hair loss, temporal hollowing or neck stiffness. Decompression surgery significantly decrease the intensity and frequency of headaches in carefully selected patients, which outweighs the burden and risk of the study procedure.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40

Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- A local headache suspected to be neuralgia caused by compression neuropathy of one of
the following peripheral nerves:
* Supraorbital nerve
* Supratrochlear nerve
* Auriculotemporal nerve
* Zygomaticotemporal nerve
* Greater occipital nerve
* Lesser occipital nerve
* Third occipital nerve

- The local headache not better accounted for by another headache diagnosis (although
coexistence is possible)

Exclusion criteria

- Known allergic reaction to bupivacaine

- Cranial defects
- Contraindications for general anesthesia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL74628.078.20