Effects of microvascular decompression of the pterygpalatine ganglion in patients with persistent, drug-resistent, Cluster headache: a pilot study.

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

Summary

ID

NL-OMON30519

Source
ToetsingOnline

Brief title
Microvascular decompression for Cluster headache.

Condition

- Headaches

Synonym
Horton's neuralgia; "suicide headache"

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cluster headache, drug-resistant, microvascular decompression, pterygopalatine ganglion

Outcome measures

Primary outcome

Primary outcome measure will be the severity of pain assessed on a Visual

Analogue Scale and the mean duration of pain per week in hours.

Secondary outcome

Secondary outcome measure will be quality of life, assessed with the SF-36

Health Survey and EuroQol questionnaire.

Study description

Background summary

Cluster headache (CH) is, although rare, a disorder well known to otolaryngologists and neurologists. CH is an invalidating condition, the pain during attacks is often described as excruciating.
The specific cause of CH remains unknown, but several mechanisms have been suggested to play a role in its etiology. One of the theories is that the pterygopalatine ganglion (PPG) is the main route for CH and its associated parasympathetic symptoms. Patients with CH can have adequate pain relief with farmacological therapy, however, some patients require surgical treatment because of persistent, drug-resistant CH. Previous studies have shown that treatment directed against the PPG, such as radiofrequent thermocoagulation, can be effective in patients with CH.
However, most treatments only provide temporary pain relief, and repeated surgical procedures are sometimed needed to establish long lasting pain relief. Examination of the anatomic relations of the PPG reveals that it lies in close contact with a remarkably tortuous portion of the maxilllary artery along its course in the pterygopalatine fossa. This fact supports the hypothesis that vascular compression of the PPG by a loop of the maxillary artery, can account for some of the manifestations of CH.
Vascular compression syndromes are associated with a variety of other disorders

such as trigeminal neuralgia, and previous studies have shown that these disorders can be treated succesfully with microvascular decompression (MVD). Our hypothesis is that microvascular decompression of the pterygopalatine ganglion may be effective in patients with CH in terms of providing long lasting pain relief.

Study objective

Main objective of this study is to assess the effects of MVD in management of patients with persistent, drug-resistant CH in terms of pain reduction and improvement of quality of life. More specific: to evaluate if MVD can provide adequate pain relief and improvement of quality of life, both short and longterm, in patients with persistent, drug-resistant CH.

Study design

A pilot study will be carried out in 6 patients with persistent chronic, drug resistant CH.
To exclude pathology as a causative factor for the pain and in order to be prepared for anatomical variations in the involved area, all patients will undergo CT and MRI or MRA.
All patients will initially be treated with lidocaine nose drops for four weeks, after which they will undergo MVD of the pterygopalatine ganglion. The follow-up period after MVD will be six months. Pain relief and improvement of quality of life will be assessed via questionnaires filled out at inclusion and at one week, 3 and 6 months follow-up.

Intervention

Microvascular decompression of the pterygopalatine ganglion by means of insertion of a piece of temporal muscle between the pterygopalatine ganglion and the maxillary artery and clipping of the artery itself; to ensure discontinuation of contact between the pterygopalatine ganglion and the maxillary artery.

Study burden and risks

Risks include the standard risks of anaesthesia and the usual risks of sinus surgery such as intra- and postoperative bleeding due to injury of the artery, postoperative sinusitis, paraesthesia of the palate and face, oroantral fistula, dental injury and theoreically entering the orbit. However, these complication rates are very low.
Burden includes a hospital admission for approximately three days and undergoing CT and MRI or MRA, as well as taking time to fill out the questionnaires at inclusion and during follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

persistent, drug-resistant, Cluster headache
patients diagnosed and treated farmacologically at Headache Group of Leiden Universitary Medical Centre

Exclusion criteria

major anatomical variations in the area of interest
disease of maxillary sinus
previous surgery in the area of interest
pain attributable to other diagnosis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	13-03-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL13904.041.06