Effects of microvascular decompression versus radiofrequent thermocoagulation of the pterygopalatine ganglion in patients with persistent, drug-resistent, Sluder*s neuralgia: a pilot study

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Main objective of this study is to assess the effects of MVD versus RF of the pterygopalatine ganglion in management of patients with persistent, drug-resistant SN in terms of pain reduction and improvement of quality of life.

Ethical review	Not approved
Status	Will not start
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON30210

Source
ToetsingOnline

Brief title
MVD versus RF of the pterygopalatine ganglion for Sluder's neuralgia

Condition

- Headaches

Synonym
pterygopalatine neuralgia, Sluder 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: microvascular decompression, pterygopalatine ganglion, radiofrequent thermocoagulation, Sluder's neuralgia

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

Sluder's neuralgia(SN) is, although rare, a disorder well known to otolaryngologists and neurologists. SN is an invalidating condition, in which pain is incessant.
The specific cause of SN remains unknown, but several mechanisms have been suggested to play a role in its etiology. The most consistent and likely theory is that the pterygopalatine ganglion (PPG) is the main route for SN and its associated parasympathetic symptoms. Patients with SN can have adequate pain relief with farmacological therapy, however, some patients require surgical treatment because of persistent, drug-resistant SN. Previous studies have shown that treatment directed against the PPG, such as radiofrequent thermocoagulation, can be effective in patients with SN.
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 the manifestations of SN.
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).

Study objective

Main objective of this study is to assess the effects of MVD versus RF of the pterygopalatine ganglion in management of patients with persistent, drug-resistant SN in terms of pain reduction and improvement of quality of life.

Study design

A pilot study will be carried out in 24 patients with persistent, drug resistant SN.
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 be randomly assigned to one of two treatment arms: 1)MVD of the pterygopalatine ganglion and 2) RF 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 risks of MVD and RF.
The risks of MVD involve 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 theoretically entering the orbit. However, these complication rates are very low.
Complications of RF are rare, and include epistaxis, hemathoma in the involved area or hypesthesia of the palate.

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-resistent Sluder's neuralgia
Persistent, drug-resistent atypical Sluder's neuralgia

Exclusion criteria

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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Ethics review

Not approved

Date:	30-10-2007
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	NL14174.041.06