Stimulation of the sphenopalatine ganglion with the ATI Neurostimulation system for cluster headache treatment

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We investigated the safety and efficacy of on-demand SPG stimulation for chronic CH (CCH).

Ethical review	Approved WMO
Status	Completed
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON44572

Source
ToetsingOnline

Brief title
SPG stimulation for cluster headache treatment

Condition

- Headaches

Synonym
cluster headache, suicide headache

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars,Autonomic Technologies Inc 3698 Haven Ave, Redwood City, CA 94063

Intervention

Keyword: cluster headache, neurostimulation, sphenopalatine ganglion

Outcome measures

Primary outcome

Therapeutic effect of the ATI neurostimulator in patients with refractory CH

headache

Secondary outcome

-Quality of life

-reduction in medication

-cost-effectiveness analysis

Study description

Background summary

The pain and autonomic symptoms of cluster headache (CH) result from activation of the trigeminal
parasympathetic reflex, mediated through the sphenopalatine ganglion (SPG).

Study objective

We investigated the safety and efficacy of on-demand SPG stimulation for chronic CH (CCH).

Study design

A, multiple CH attack study of an implantable on-demand SPG neurostimulator was conducted in
patients suffering from refractory CCH. The design is cross-over, each patient was randomly treated with full or placebo
stimulation. Pain relief at 15 minutes following SPG stimulation and device- or procedure-related serious adverse
events (SAEs) were evaluated

Intervention

Implantation of the ATI neurostimulator in the sphenopalatine ganglion

Study burden and risks

On-demand SPG stimulation using the ATI Neurostimulation System is an effective novel therapy for CCH
sufferers, with dual beneficial effects, acute pain relief and observed attack prevention, and has an acceptable safety
profile compared to similar surgical procedures (reference Schoenen et al)

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

-18-65 years old.
-classified with chronic cluster headache ICHD-3 criteria 3.1.2
-reported headache frequentie of 10 weekly
-Patient reported dissatisfaction with current headache treatments.
-Patient was able to distinguish cluster headaches from other headaches.
-knowledge dutch language

Exclusion criteria

-Patient had a change in type or dosage of preventive headache medications within one month of enrollment.
-Women of childbearing age who were pregnant, nursing, or not using contraception.
-Patient had undergone facial surgery in the area of the pterygopalatine fossa or zygomaticomaxillary buttress ipsilateral to the planned implant site within the last four months.
-Patient had been treated with radiation to the facial region within the last six months.
-Patient had been diagnosed with any major infectious processes including osteomyelitis or primary or secondary malignancies of the face that were active or required treatment in the past six months.
Patient had another significant pain problem that might confound the study assessments in the opinion of the investigator.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	31-07-2015
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Implantable ATI Neurostimulator NS-100
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21021
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50300.029.14
OMON	NL-OMON21021