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

Published: 21-01-2015
Last updated: 19-03-2025

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

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|---|---|
| **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

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

## Ethics review

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|---|---|
| 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: NTR
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL50300.029.14 |
| OMON | NL-OMON21021 |