Occipital nerve stimulation: Real-world long-term clinical follow up in medically intractable cluster headache

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Primary Objective: To assess real-world long-term efficacy and tolerability of occipital nerve stimulation (ONS) in medically intractable chronic cluster headache patients Secondary Objectives: - To obtain real world data of effect of ONS on quality...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51040

Source
ToetsingOnline

Brief title
Long term follow-up of ONS in MICCH

Condition

- Other condition
- Headaches

Synonym
Hortons neuralgia, neuralgia of Horton

Health condition

Hoofdpijn/chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NVT

Intervention

Keyword: neuromodulation, neurostimulation, occipital nerve, ONS

Outcome measures

Primary outcome

Average number of weekly attacks 1, 2 and 5 years after ONS implantation

compared to baseline

Secondary outcome

- Average score on the SF-36 and HADS 1, 2 and 5 years after ONS implantation

compared to baseline

- Average attack intensity 1,2 and 5 years after ONS implantation compared to

baseline

- Use of prophylactic medication 1,2 and 5 years after ONS implantation

compared to baseline

- Average weekly use of attack medication and oxygen 1,2 and 5 years after ONS

implantation compared to baseline

- Side effects

- Number of revisions and battery replacements necessary

- Drop-out during the 5 years study period

Study description

Background summary

Occipital nerve stimulation (ONS) is a relatively new, invasive, reversible preventive treatment for medically intractable chronic cluster headache (MICCH) and has recently been approved for reimbursement by the Dutch health authority. This approval was based on the preliminary positive results of the *occipital nerve stimulation in medically intractable chronic cluster headache* (ICON) trial that investigated a high vs low stimulation protocol. Since ONS is a relatively new treatment method, real life clinical follow up data to determine effect and tolerability is warranted. Furthermore, this data can be used to identify possible factors predicting effect.

Study objective

Primary Objective:
To assess real-world long-term efficacy and tolerability of occipital nerve stimulation (ONS) in medically intractable chronic cluster headache patients

Secondary Objectives:
- To obtain real world data of effect of ONS on quality of life
- To obtain real world data of effect of ONS on anxiety and depression
- To identify possible factors predicting effect
- To evaluate the use of acute.medication and oxygen use during ONS treatment

Study design

Multicenter observational study

Study burden and risks

The risks of the proposed study are very low since this is an observational study. It is very important to gain a detailed clinical follow up of this new treatment to determine real world efficacy, identify possible predictive factors, and to gain a better understanding of the mechanism of action.

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

Diagnosis of MICCH, according to the ICHD-III criteria and the ICON trial guidelines:
o No relevant effect on maximum dosage or
o Severe side effect or
o Contra-indication for
At least three prophylactic drugs including
* Verapamil
* Lithium
* Topiramate
Patients should be receiving ONS implantation as part of clinical care
Patients have to be aged 18 years or older
Adequate control of the Dutch language
The ability and possibility to use an e-device

Exclusion criteria

NA

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL75958.058.20