

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

CCMO

ID

NL75958.058.20