Occipital nerve stimulation in patients with medically intractable chronic cluster headache:
A PET study

Published: 01-09-2011
Last updated: 29-04-2024

The focus of this present study will be to better understand the mechanism of ONS in MICCH. The primary objective of this study is to investigate the putative differences in rCBF at 6 months follow-up compared to baseline between responders of ONS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON39533

Source
ToetsingOnline

Brief title
ICON PET

Condition

- Headaches

Synonym
cluster headache

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: er wordt subsidie aangevraagd bij de hersenstichting en fonds nuts ohra en er is gedeeltelijke subsidie van Medtronic,Medtronic Trading NL BV

Intervention

Keyword: chronic cluster headache, medically intractable, occipital nerve stimulation, PET imaging

Outcome measures

Primary outcome

The primary endpoint will be the difference in rCBF following 6 months of ONS

compared to their baseline rCBF difference,

Secondary outcome

The secondary endpoint is the difference in scores on subjective

questionnaires and to explore the putative differences in rCBF between high

(100%) stimulation and low (30%) stimulation.

Study description

Background summary

Cluster headache (CH) is a primary headache disorder characterized by recurrent short-lasting attacks (15 to 180 minutes) of excruciating unilateral periorbital pain accompanied by ipsilateral cranial autonomic signs. The 1-year prevalence of CH is about 0.1 %, the male: female ratio is 3:1. The majority of patients have cluster periods of weeks to months with frequent attacks which are alternated with symptom-free periods of months to several years; the episodic form of CH. In about 10% of patients the CH is chronic (CCH) in which either no remission occurs within 1 year or the remissions last less than 1 month. At least 10 % of CCH patients are refractory to medical treatment or cannot tolerate the treatments.

Recent pilot studies suggest that occipital nerve stimulation (ONS) in medically intractable CCH (MICCH) might offer an effective alternative to medical treatment. There are no randomised clinical trials and a placebo effect cannot be excluded. Long term tolerability is known from other indications. The

efficacy of ONS in MICCH will be evaluated in the ICON study (Intractable chronic Cluster headache Occipital Nerve stimulation study, see protocol 10.016).

Here we propose a clinical PET study in patients included in the ICON study in the Netherlands to unravel the mechanism of ONS in patients suffering MICCH.

Study objective

The focus of this present study will be to better understand the mechanism of ONS in MICCH. The primary objective of this study is to investigate the putative differences in rCBF at 6 months follow-up compared to baseline between responders of ONS and non responders of ONS. The secondary objective is to explore the putative differences in rCBF between high (100%) stimulation and low (30%) stimulation.

Study design

This study will be embedded in the international ICON study. As it is known from the literature that ONS takes weeks to months to have the optimum effect, we decided to scan at baseline (before randomisation and implantation of the device and stimulation, but after the baseline period of 3 months) and after 6 months of stimulation (two different conditions of stimulation: 30% and 100% stimulation as explained in the protocol NL30794058.10) in on condition. So each patient will get 2 PET scans. Because we only want to investigate the effect of the stimulation (not the headache) on the rCBF, patients have to be pain free two hours before scanning.

Intervention

PET scan

Study burden and risks

Known risks of placing the catheter for the PET scan can be a hematoma. The total amount of radioactivity will be 0,7 milliSievert (mSv) per [15O] H2Owater scan. This means a total amount of radioactivity of 1,4 mSv. The total amount of radioactivity that everybody is exposed to in one year, because of background radiation from the universe and environment, is 2-2,5 mSv. If patients have been exposed to radiation recently, the researcher will check if the total amount will not exceed 10 mSv, which is the total amount of radiation accepted in The Netherlands in these circumstances.

Patients included in the Netherlands will have to travel twice to the Vrije Universiteit Medisch Centrum (VUMC), Amsterdam, The Netherlands for a PET scan. The first PET scan will be performed at the end of baseline period and after

the decision of the study neurologist that the patient is still eligible and will be randomised. An MRI scan of the brain will also be performed during this first visit. The second visit will be after 6 months of stimulation, just before the end of the blinded period of the trial. The PET scan of this second visit will be performed in on condition
Travel expenses will be reimbursed and patients will receive 125 euro per PET scan.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participants of the ICON study
see for details ICON study protocol

Exclusion criteria

exclusion criteria ICON study
contra indications PET scan

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2014
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	

Date:	11-02-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
ClinicalTrials.gov	NCT01151631
CCMO	NL36555.058.11

Study results

Date completed:	14-04-2016
Actual enrolment:	24

Summary results
Trial is onging in other countries