Clusterheadache Implantation and Neurostimulation Technology and Health Assessment

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21021

Source
Nationaal Trial Register

Brief title
CINTHA

Health condition

cluster headache
clusterhoofdpijn
sphenopalatine
stimulator
neurostimulator

Sponsors and support

Primary sponsor: Stichting VU-VU Medisch Centrum
De Boelelaan 1117
1081 HV Amsterdam
Source(s) of monetary or material Support: ATI
Grant innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

To determine the therapeutic effect of the ATI NeurostimulationSystem in patients with drug-resistant chronic cluster headaches in the Netherlands

Secondary outcome

To demonstrate changes in quality of life in patients treated with the ATI NeurostimulationSystem

To demonstrate a reduction in acute and preventative pharmacological treatment in patients treated with the ATI NeurostimulationSystem

To determine the cost-effectiveness of implementation of the ATI NeurostimulationSystem per chronic cluster headache patient

Study description

Background summary

Cluster headache is a rare condition characterized by an extremely intense pain localised unilaterally around the eye. Aim of this study is to validate neurostimulation treatment with the ‘ATI Neurostimulation System’ for patients with chronic cluster headaches and to assess the cost-effectiveness of this treatment in a clinical setting. Previous studies have shown ATI neurostimulation to be an effective treatment for chronic cluster headaches. However, in the Netherlands this method is not a standard treatment for cluster headaches and is not covered by basic medical insurance in the Netherlands.

For this study, the ATI Neurostimulation System will be implanted in 35 patients who cannot be treated with conventional pharmacological treatment due to either drug resistance or severe side effects. The neurostimulator will be implanted at the zygomatico-alveolar crest. The electrode of the device will be localised near the sphenopalatinal ganglion in the pterygopalatinal fossa. The patient can activate the neurostimulator on demand using a remote control. The device is programmed to administer either a full stimulation or a Sham stimulation in a 2 : 1 ratio. Patients will use the system for a three month period. During these three months, data on experienced pain intensity, use of pain medication and quality of life are collected.

Study design

Work phase 1

In the first 6 months, preparations for patient inclusion will be made as well as public announcements for patient recruitment.

Work phase 2

After completion of the preparation phase, the inclusion of patients will start. Upon inclusion, participating patients and their practitioners will be instructed and informed properly. In this phase, baseline information will be collected regarding clinical characteristics of the chronic cluster headaches, medication use, quality of life and the direct and indirect medical expenses associated with the condition.

Work phase 3

After completion of the three months of baseline data collection, the stimulator module is implanted. The settings of the device for optimal pain reduction vary per patient and are adjusted prior to the experimental stage.

Work phase 4

After implantation of the module, patients will start a therapy-validation phase to confirm the therapeutic results from previous studies with the ATI NeurostimulationSystem. This phase will last 3 months.

Work phase 5

After the therapy validation phase, patients will enter the follow-up phase, in which patients continue with the therapy while long-term therapeutic potency is assessed. This phase will last 9 months. During this phase, medication use is being reduced, in part guided by the therapeutic results experienced in WP4.

Work phase 6

In the last work phase, the cost-effectiveness of the ATI NeurostimulationSystem with respect to placebo-treatment is analysed. Results of the trial will be published. When a positive outcome of the clinical validation and cost-effectiveness analysis can be demonstrated, an implementation plan will be made to come to a national implementation of this new treatment modality in the Netherlands.

After completion of a work phase patients will proceed immediately to the subsequent work phases. Therefore, there will be a mostly parallel execution of Work Phases 2 through 5.

Intervention

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conventional pharmacological treatment due to either drug resistance or severe side effects. The neurostimulator will be implanted at the zygomatico-alveolar crest. The electrode of the device will be localised near the sphenopalatinal ganglion in the pterygopalatinal fossa.

Contacts

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Eligibility criteria

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 type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2015
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-12-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44572
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4175
NTR-old	NTR5588
CCMO	NL50300.029.14
OMON	NL-OMON44572

Study results