GM-11: A randomized, multicentre, double-blind, parallel, sham-controlled study of the gammaCore®-R, a non-invasive neurostimulator device, for the prevention of episodic migraine

Published: 30-09-2015
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Primary objective:The primary objective is the difference between the gammaCore®-R and the sham treatment groups in mean reduction in number of episodic migraine days during the last four weeks in the twelve-week randomized period compared with the...

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

Summary

ID

NL-OMON42692

Source
ToetsingOnline

Brief title
GM-11

Condition

- Headaches

Synonym
episodic migraine

Research involving
Human

Sponsors and support

Primary sponsor: electroCore LLC
Source(s) of monetary or material Support: electroCore LLC

Intervention

Keyword: episodic migraine, gammaCore®-R device, neurostimulator

Outcome measures

Primary outcome

Diary- number of migraine/headache days

Secondary outcome

HIT-6

MIDAS

EQ-5D-5L

Medication use and change Adverse event

Study description

Background summary

Despite advances in the medical and surgical management of migraine, clinical data have revealed a significant proportion of patients who do not adequately respond to pharmacologic intervention and remain symptomatic. Approximately 40% of all migraine attacks do not adequately respond to a given triptan or any other substance.4 In addition, many of the current therapeutic options come with significant risks ranging from GI and vascular injury to birth defects and surgical complications.
Alternative therapy that may be effective for treating migraines could involve electrical stimulation of vagal neural pathways involved in mediating the causes and symptoms of migraine.

Study objective

Primary objective:
The primary objective is the difference between the gammaCore®-R and the sham

treatment groups in mean reduction in number of episodic migraine days during the last four weeks in the twelve-week randomized period compared with the four week run-in period

Secondary objectives:
* Rate of responders for the gammaCore®-R group compared to the sham group. A responder is defined as recording at least 50% reduction in migraine days during the last four weeks in the twelve-week randomization period compared to the four week run-in period.
* Difference between the gammaCore®-R and sham treatment groups in mean reduction in number of headache days during the last four weeks in the twelve-week randomized period compared to the four week run-in period.
* Difference between the gammaCore®-R and the sham treatment groups in the mean reduction in acute headache medications taken during the last four weeks in the twelve- week randomized period compared to the four week run-in period.
* Compare improvement in headache disability using Headache Impact Test-6 (HIT-6)
* Any acute medication use in all periods
* Compare improvement in Migraine Disability Assessment (MIDAS)
* Compare Quality of Life EQ-5D-5L
* Reduction of number of headache/migraine days in the open label period
* Adverse events

Study design

The study is a prospective double blind, randomized, sham-controlled, multi-center investigation designed for comparison of two parallel groups, gammaCore®-R (active treatment) and a sham (inactive) treatment.
The study period will begin with a four week run-in period, during which there is no investigational treatment. The purpose of the run-in period will be observation for baseline comparison.
The run-in period will be, followed by a 12 week randomized period when the subjects will be randomized (1:1) to either active treatment or sham (inactive) treatment.
The randomized period will be followed by a 24 week open label period, where the subjects in the sham treatment group will switch in treatment assignment and receive a gammaCore®-R and the gammaCore®-R group will continue to receive an active treatment.

Intervention

One group receives an active device, the other receives a sham-device.

Study burden and risks

The gammaCore®-R is being trialed for the prophylactic treatment of episodic

migraine. The anticipated benefits include:
* Significant reduction of number of migraine/headache days
* Improved quality of life.
* Reduced medication for acute migraine rescue medication
There are no significant risks identified with the participation in this study however study subjects can rarely experience transient symptoms such as:
* Shortness of breath (dyspnoea), hoarseness or change in voice during treatment
* Muscle twitching, discomfort, or pain during
* Tingling, pricking or a feeling of *pins and needles* on the skin where the device is
applied (paraesthesia or dysaesthesia) lasting beyond the treatment period
* Skin irritation/inflammation
* Fainting (Syncope) during treatment
* Dizziness

All subjects must undergo training at the clinic before starting treatment with the device.

The benefits of this study are estimated to outweigh the risks as the subject*s improvement is expected to be considerably greater than any expected side effects. The goal of this study is to decrease number of headache days resulting in a better quality of life for the subject.
A risk analysis was performed for the sham device. As a result, there were no major or moderate risks and/or hazards identified regarding vagus nerve stimulation with the sham device that are not identified above

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

Inclusion Criteria
1. Is between the ages of 18 and 75 years.
2. Has been previously diagnosed with migraine (with or without aura) in accordance with the ICHD-3 Beta Classification criteria.
3. Experience between 5 and 12 migraine days per month (over the last 4 months) with at least 2 of the migraines lasting more than 4 hours.
4. Has age of onset of migraine less than 50 years old.
5. Agrees not to use any migraine prevention treatments (including Botox injections) and/or medications (exclusive of medications taken for acute relief of migraine symptoms).
6. Agrees to refrain from initiating or changing the type, dosage or frequency of any prophylactic medications for indications other than migraine that in the opinion of the clinician may interfere with the study objectives (e.g. antidepressant, anti convulsant, beta blockers, etc.).
7. Agrees to use the gammaCore®-R device as intended, follow all of the requirements of the study including follow-up visit requirements, record required study data in the subject dairy, and other self-assessment questionnaires.
8. Is able to provide written Informed Consent.

Exclusion criteria

Exclusion Criteria
Subjects meeting any of the following criteria cannot be included in this research study
1. Has a concomitant medical condition that will require oral or injectable steroids during the study.
2. Has a history of any intracranial aneurysm, intracranial haemorrhage, brain tumour or significant head trauma.
3. Has a structural abnormality at the gammaCore®-R treatment site (e.g lymphadenopathy

previous surgery or abnormal anatomy).
4. Has pain at the gammaCore®-R treatment site (e.g. dysesthesia, neuralgia and/or cervicalgia).
5. Has other significant pain problem (e.g. cancer pain, fibromyalgia or other head or facial disorder) that in the opinion of the investigator may confound the study assessments
6. Has known or suspected severe cardiac disease (e.g. symptomatic coronary artery disease, prior myocardial infarction, congestive heart failure (CHF)).
7. Has known or suspected severe cerebrovascular disease, (e.g. prior stroke or transient ischemic attack, symptomatic carotid artery disease, prior carotid endarterectomy or other vascular neck surgery).
8. Has an abnormal baseline Electrocardiogram (ECG) e.g. second and third degree heart block, prolonged QT interval, atrial fibrillation, atrial flutter, history of ventricular tachycardia or ventricular fibrillation, or clinically significant premature ventricular contraction).
9. Has had a cervical vagotomy.
10. Has uncontrolled high blood pressure (systolic >160 diastolic > 100 after 3 repeated measurements within 24 hours).
11. Is currently implanted with an electrical and/or neurostimulator device (e.g. cardiac pacemaker or defibrillator, vagal neurostimulator, deep brain stimulator, spinal stimulator, bone growth stimulator cochlear implant, Sphenopalatine ganglion stimulator or Occipital nerve stimulator).
12.Has been implanted with metal cervical spine hardware or has a metallic implant near the gammaCore®-R stimulation site.
13.Has a known history of suspicion of secondary headache.
14.Has a history of syncope (within the last five years).
15. Has a history of seizures (within the last five years).
16. Has a known or suspicion of substance abuse or addiction (within the last 5 years).
17. Is using marijuana (including medical marijuana) for any indications, more than twice a month.
18. Currently takes simple analgesics or non-steroidal anti-inflammatory drugs (NSAIDs) greater than 15 days per month or triptans, ergots or combined analgesics greater than 10 days per month for headaches or other body pain.
19. Currently takes prescription opioids greater than 2 days per month for headaches or body pain.
20. Has taken medications for migraine prophylaxis in the previous 30 days.
21. Has previous diagnosis of medication overuse headache (MoH), which has reverted to episodic migraine within the last 6 months.
22. Meets the ICHD-3 Beta Classification criteria for chronic migraine (> 15 headache days per month).
23. Has failed an adequate trial (two months or greater) of at least 3 classes of a drug therapy for the prophylaxis of migraine.
24. Has had surgery for migraine prevention.
25. Has undergone nerve block (occipital or other) in the head or neck within the last 2 months.
26. Has received Botox injections within the last 6 months.
27. Is pregnant or thinking of becoming pregnant during the study period, or of childbearing years and is unwilling to use and accepted form of birth control.
28. Is participating in any other therapeutic clinical investigation or has participated in a

clinical trial in the preceding 30 days.
29. Belongs to a vulnerable population or has any condition such that his or her ability to provide informed consent, comply with the follow-up requirements, or provide self-assessments is compromised (e.g. homeless, developmentally disabled and prisoner).
30. Is a relative of or an employee of the investigator or the clinical study site.
31. Has psychiatric or cognitive disorder and/or behavioral problems which in the opinion of the clinician may interfere with the study.
32. Has previously used the gammaCore® device.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	gammaCore-R
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-09-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-12-2015
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
ClinicalTrials.gov	NCT02378844B
CCMO	NL53159.058.15

Study results

Date completed:	02-12-2016
Actual enrolment:	40