Trial Description

Title

Transcutaneous Vagus Nerve Stimulation for the treatment of chronic migraine

Trial Acronym

cMPsCMI01

URL of the trial

http://www.klinikum.uni-muenchen.de/Klinik-und-Poliklinik-fuer-Neurologie/de/Klinik/Neurologische_Poliklinik/Kopfschmerz_-_Ambulanz/Studien/index.html

Brief Summary in Lay Language

Invasive vagus nerve stimulation (VNS) is an approved treatment in drug-resistant epilepsy. The development of a medical device to apply transcutaneous vagus nerve stimulation (t-VNS) meets the demand for a non-invasive therapy with low side-effects. During t-VNS electrical pulses are delivered via electrodes which are placed on the skin of the outer ear. A reduction in epileptic seizure frequency is observed both after VNS and after the recently developed t-VNS. Furthermore several clinical case series describe a headache reducing effect of VNS. However, the method is not applied routinely for the treatment of headache at the moment. The study, which is going to begin in the near future, is conducted to elucidate the possible reduction in both the frequency and the intensity of migraine attacks after the application of the medical device. The patient will receive the non-invasive device from the investigator and apply it self-dependently for 4 to maximum 5 hours daily. The prophylactic efficacy of the therapy will be judged using a patient diary. Depending on his participation in the optional follow-up phase the patient will have to participate in 6 to 7 clinical visits during the study phase, which is going to last 4 to 7 months for each participant.

Brief Summary in Scientific Language

Invasive vagus nerve stimulation (VNS) is an approved treatment in drug-resistant epilepsy. The t-VNS® technology, a non-invasive treatment, uses the fact that the auricular branch of the vagus nerve supplies the cymba conchae of the human ear exclusively. A specifically developed ear electrode guarantees that electrical impulses from the pulse generator, which is connected by cable, can be accurately delivered transcutaneously. The excitatory projection of the cervical and the auricular branches of the vagus nerve to the nucleus of the solitary tract has been shown to activate similar subcortical and cortical areas in the brain. Literature review shows several examples of cases where the invasive VNS seemed to be effective in treating different types of headache. Therefore, the study is going to be conducted in order to demonstrate t-VNS to be an effective option for the treatment of chronic migraine. The influence of t-VNS both on the frequency of migraine attacks and on the intensity of pain during these attacks as well as on the quality of life of patients are the most important outcome parameters of the clinical trial.

Organizational Data

- DRKS-ID: **DRKS00003681**
- Date of Registration in DRKS: **2012/03/23**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **510-11 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

- EUDAMED-No.
  (for studies acc. to Medical Devices act): **CIV-11-09-002381**

Health condition or Problem studied

- ICD10: **G43.3 - Complicated migraine**

Interventions/Observational Groups

- Arm 1: **active group: transcutaneous, non-invasive electrical stimulation of the auricular branch of the vagus nerve by using a specific ear electrode. A cable connects this ear electrode with the stimulation unit, which has the size of a mobile phone. In the active arm impulses will be given in a high frequency.**
- Arm 2: **active control group: Stimulation with the same kind of medical device and at the same site as done in the active group, but with a lower impulse ferquency.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor, data analyst**

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Proof a the therapeutic efficacy of t-VNS for chronic migraine estimated via the number of headache days per 28 days.

Secondary Outcome

Recording of the headache related burden. Recording of the amount of acute medication needed. Recording of the headache intensity. Recording of any adverse events of t-VNS. estimated via: headache intensity during headache days. Consumption of acute medication. Number of migraine related consultations. MIDAS. HIT-6-Score. Mode and number of AEs and SAEs.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Oberbayerisches Kopfschmerzzentrum der LMU München, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/17**
- Target Sample Size: **98**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2012/04/17**

Target Sample Size: **98**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

males and females from 18 to 70 y. Patients suffering from chronic migraine according to ICHD-II 1.5.1. Duration of disease of minimum 3 months. Prophylactic medication on a stable regimen for minimum 1 month or 5 half-lives (the longer duration will be counted). Stable agent(s) for acute medication during baseline period. Patient diary kept properly for minimum 20 out of 28 days, minimum 15 headache days with minimum 4 hours of headache, extrapolation to 28 days.

Exclusion criteria

Participation in another clinical trial during the last 4 weeks before study entry. Pregnant or breastfeeding women. Suffering from craniomandibular dysfunction or fibromyalgia. Other primary/secondary headache disorders (e.g. cluster headache, trigeminal neuralgia, etc.). Beck depression inventory > 24 at date of inclusion. Other chronic neurological or psychiatric disorders (e.g. psychoses) which impair study participation. Dependance on opioids or benzodiazepines. Anatomical or pathological abnormalities at the left ear. Actual process of retirement.

Addresses

- **Primary Sponsor**

cerbomed GmbH
Mr. Dr. Andreas Hartlep
Henkestr. 91
91052 Erlangen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **andreas.hartlep at cerbomed.com**

Primary Sponsor

cerbomed GmbH
Mr. Dr. Andreas Hartlep
Henkestr. 91
91052 Erlangen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **andreas.hartlep at cerbomed.com**
URL: **[---]***

■ **Contact for Scientific Queries**

cerbomed gmbH
Mr. Dr. Andreas Hartlep
Henkestr. 91
91052 Erlangen
Germany

Telephone: **+49 9131 9202 760**
Fax: **+49 9131 9202 7692**
E-mail: **andreas.hartlep at cerbomed.com**
URL: **www.cerbomed.com**

■ **Contact for Public Queries**

Oberbayerisches Kopfschmerzzentrum der LMU München
Ms. PD Dr. med. Ruth Ruscheweyh
Marchioninistr. 15
81377 München
Germany

Telephone: **+49 89 7095 3907**
Fax: **+49 89 7095 3677**
E-mail: **Ruth.Ruscheweyh at med.uni-muenchen.de**
URL: **http://www.klinikum.uni-muenchen.de/Klinik-und-Poliklinik-fuer-Neurologie/de/Klinik/Neurologische_Poliklinik/Kopfschmerz_-_Ambulanz/index.html**

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

cerbomed GmbH
Henkestr. 91
91052 Erlangen
Germany

Commercial (pharmaceutical industry, medical engineering industry, etc.)

cerbomed GmbH
Henkestr. 91
91052 Erlangen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/11/30**

Trial Publications, Results and other documents

- Paper **t-VNS in patients with chronic migraine**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*