

Study comparing best medical practice with or without vagus nerve stimulation (VNS) therapy in pharmaco-resistant partial epilepsy patients

Submission date 09/02/2005	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
Registration date 18/02/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 22/03/2016	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00522418

Protocol serial number

E-100

Study information

Scientific Title

An open Prospective randomised Long-term Effectiveness study, comparing adjunctive vagus nerve stimulation (VNS) therapy with best medical practice in patients with pharmaco-resistant partial epilepsy aged 16 and above

Acronym

PuLsE

Study objectives

This is an open prospective randomised and comparative long-term effectiveness study, comparing adjunctive vagus nerve stimulation (VNS) therapy with best medical practice in patients with pharmaco-resistant partial epilepsy. The minimum age of enrolment is 16 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of "Hôpital Neurologique" in Lyon (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale), 20/12/2005, ref: A 05-073

Study design

Randomised multicentre controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Epilepsy

Interventions

Intervention:

VNS therapy is implanted under the left clavicle and typically this is done in 1 hour. The electrode is tunneled from the device sub-pectoral pocket to the left vagus nerve.

Control:

Best medical practice.

Intervention Type

Device

Primary outcome(s)

1. To show over time that the efficacy of adding VNS therapy is non-inferior to the efficacy obtained with best medical practice
2. To show over time superiority of VNS therapy in health outcomes compared with best medical practice using the 89-item Quality of Life in Epilepsy (QOLIE-89) inventory

Key secondary outcome(s)

To compare the efficacy and health outcomes of both treatment arms using other assessments focused on:

1. Seizure freedom
2. Mood
3. Safety/tolerability
4. Drug changes
5. Retention rate
6. Compliance

Completion date

31/12/2009

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

To be eligible for enrolment in the study, patients must meet all of the following criteria:

1. Patient has confirmed partial onset seizures
2. Seizure activity is not adequately controlled by patient's current antiepileptic drug (AED) regimen
3. Patient is age 16 up to age 75, either sex
4. Patient is able to give accurate seizure counts and health outcomes information
5. Patient has previously failed at least 3 AEDs in single or combination use
6. During baseline, patient should take 1 AED
7. Patient should have confirmed epilepsy for a minimum of 2 years
8. Patient's AED regimen is stable for at least one month prior to enrolment
9. Patient has at least one partial onset seizure per month
10. Patients with an intelligence quotient (IQ) greater than or equal to 70
11. Patient or legal guardian understands study procedures and has voluntarily signed an informed consent in accordance with institutional policies

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients with any of the following will not be eligible for enrolment:

1. Patient has a history of pseudoseizures
2. Patient has had more than one episode of status epilepticus (SE) in the past 12 months

3. Patient has idiopathic or difficult to classify seizures
4. Patient has ever received direct brain stimulation (cerebella or thalamic) for treatment of epilepsy
5. Patient has had a unilateral or bilateral cervical vagotomy
6. Patient has a history of non-compliance for seizure diary completion
7. Patient has taken an investigational drug within a period of 3 months prior to inclusion
8. Patient is currently using another investigational medical device
9. Patient has a significant cardiac or pulmonary condition currently under treatment
10. Patient has other progressive neurological disease, significant central nervous system (CNS) disease or injury, or cervical fracture that makes implantation of the VNS therapy system difficult
11. Patient has previously undergone brain surgery
12. Patient has a demand cardiac pacemaker, implantable defibrillator, or other implantable stimulator
13. Patient currently lives more than two hours away from the study site or plans to relocate to a location distant from the study site within one year of enrolment in the study

Date of first enrolment

17/02/2006

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

Belgium

Canada

France

Germany

Italy

Netherlands

Norway

Spain

Sweden

Study participating centre

Hôpital Neurologique

Lyon

France

69003

Sponsor information

Organisation

Cyberonics Europe SA/NV (Belgium)

Funder(s)

Funder type

Industry

Funder Name

Cyberonics Europe SA/NV (Belgium) - educational grant to the academic centre collecting the data

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No