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

Submission date 09/02/2005	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/02/2005	**Overall study status** Stopped	
Last Edited 22/03/2016	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00522418

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
17/02/2006

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

Age group
Adult

Sex
Both

Target number of participants
366

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
Belgium

Canada

France

Germany

Italy

Netherlands

Norway

Spain

Sweden

United Kingdom

Study participating centre
Hôpital Neurologique
Lyon
France
69003

Sponsor information

Organisation
Cyberonics Europe SA/NV (Belgium)

Sponsor details
Belgicastraat 9
Zaventem
Belgium
1930

Sponsor type
Industry

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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