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French vagus nerve stimulation (VNS) epilepsy registry

Submission date
04/03/2013

Recruitment status
No longer recruiting

Registration date
26/04/2013

Overall study status
Completed

Last Edited
17/01/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Vagus Nerve stimulation (VNS) Therapy has been CE marked for the treatment of epilepsy since 1994. This study is designed to assess clinical course and outcomes for patients diagnosed with partial or generalized seizures that are refractory (do not respond) to antiepileptic medication treated with standard of care including adjunctive VNS Therapy for patient with epilepsy.

Who can participate?
All patients who agree to be treated by VNS Therapy should take part to the study except if the patient declines participation.

What does the study involve?
If a patient agree to take part, he/she will be followed for about 27 months (2 visits pre-implant & 4 visits post-implantation at 6, 12, 18 and 24 months). During the study, the following items will be assessed: Seizure frequency, seizure severity, quality of life, health status and safety.

What are the possible benefits and risks of participating?
Patient may benefit from more frequent visits with their treating physician. There are no additional risks for patients in this study other than the loss of confidentiality and those risks associated with receiving a VNS Therapy device.

Where is the study run from?
The study will take place in 15 preselected hospitals across France

When is the study starting and how long is it expected to run for?
January 2013 to June 2017

Who is funding the study?
LivaNova Belgium N.V.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
E-104

Study information

Scientific Title
A post-market, long-term, prospective, observational, multi-site outcome study to assess the clinical course and seizure reduction of patients treated with adjunctive vagus nerve stimulation therapy in France

Acronym
E-104

Study objectives
This post-market observational study is designed to assess clinical course and outcome for patients diagnosed with partial or generalized seizures that are refractory to antiepileptic medications treated with standard of care including adjunctive VNS Therapy. Seizure frequency, seizure severity, quality of life, health status and safety will be evaluated. The results of this study will provide data to guide physicians and their patients in the use of the VNS Therapy for patients with epilepsy. The data being collected is not for the purposes of confirmatory assessment.

The primary objective is to evaluate the effectiveness of VNS Therapy in patients with drug resistant epilepsy treated with adjunctive VNS Therapy over a 2 year post-implant period in France.

The secondary objectives are to assess the effectiveness endpoints, safety and tolerability of VNS Therapy in patients with epilepsy treated with adjunctive VNS Therapy over a 2 year post-implant period in France.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board: CPP île de France 3, 05/12/2012, ref: SC2995

Study design
Post-market long-term prospective observational multi-site study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Drug-resistant epilepsy

Interventions
Data from all investigative sites will be combined in the computation of summary statistics. Data will be summarized with respect to each of the parameters that include enrollment and disposition summaries, demographics and baseline disease characteristics. VNS Therapy effectiveness measures and safety measures.

If a patient agree to take part, he/she will be followed for approximately 27 months (2 visits pre-implant & 4 visits post-implantation at 6, 12, 18 and 24 months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Response rate, measured using a summary of participant seizure diary at baseline (pre-implant)), and 6, 12, 18 and 24 months post implant

Key secondary outcome(s))
Measured at baseline (pre-implant)), and 6, 12, 18 and 24 months post implant:
1. Visit-wise response rate – percent (proportion) of patients who achieved a reduction of ≥ 50% in seizure frequency of all seizure types combined from baseline at each visit time-point after VNS device implant, measured by seizure frequency data in seizure diary
2. Seizure frequency of all seizures combined, measured using a seizure diary
3. Seizure severity, measured using the NHS3 scale
4. Health status, measured using EQ-5D and EQ-5D-Y
5. Quality of life, measured using Qolie-31-P and Qolie-AD-48

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. All newly patients implanted with a VNS device
2. Patients must have received the information letter and agreed that their data will be collected and transmitted to Cyberonics for analysis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Does not meet inclusion criteria
The investigator should refer to the instructions for VNS Therapy use

Date of first enrolment
21/01/2013

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
France

Study participating centre
Centre Hospitalier Sainte-Anne
Paris
France
-

Study participating centre
Fondation Ophtalmologique Adolphe de Rothschild
Paris

France
-

Study participating centre
Clinique de l'Europe
Rouen
France
-

Study participating centre
Centre Hospitalier de Béthune
Béthune
France
-

Study participating centre
Centre Hospitalier Régional Universitaire de Lille
Lille
France
-

Study participating centre
Etablissement médical de la Teppe
Tain l'Hermitage
France
-

Study participating centre
Hôpital Henri Gastaut
Marseille
France
-

Study participating centre
Centre Hospitalier Universitaire de Dijon
Dijon
France
-

Study participating centre
Centre Hospitalier Universitaire de Limoges
Limoges
France
-

Study participating centre
Centre Hospitalier Universitaire de Toulouse
Toulouse
France
-

Study participating centre
Centre Hospitalier Universitaire de Bordeaux
Bordeaux
France
-

Study participating centre
Centre Hospitalier Universitaire de Nantes
Nantes
France
-

Study participating centre
Centre Hospitalier Universitaire de Nîmes
Nîmes
France
-

Study participating centre
Centre Hospitalier Universitaire d'Angers
Angers
France
-

Study participating centre

Hôpitaux de Paris - Campus Necker
Paris
France
-

Sponsor information

Organisation
LivaNova Belgium N.V.

ROR
https://ror.org/053mjnp36

Funder(s)

Funder type
Industry

Funder Name
LivaNova Belgium N.V.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The data will be stored on a secured server at the sponsor's site and won't be accessible via a weblink.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes