

French vagus nerve stimulation (VNS) epilepsy registry

Submission date 04/03/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/01/2017	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?
Mr Wim Van Grunderbeek
Clinical Department
+32 (0)2 720 95 93

Contact information

Type(s)
Scientific

Contact name
Dr Elizabeth Landre

Contact details
CH Sainte-Anne
rue Cabanis 1
Paris
France
75014

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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 $\geq 50\%$ 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

Overall study start date

21/01/2013

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

Age group

All

Sex

Both

Target number of participants

150 patients. The enrollment period will end when 150 implanted patients have a least one follow-up assessment post-baseline

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.

Sponsor details

Program Manager Neuromodulation

Ikaroslaan 83

Zaventem

Belgium

1930

Sponsor type

Industry

ROR

<https://ror.org/053mjnp36>

Funder(s)

Funder type

Industry

Funder Name

LivaNova Belgium N.V.

Results and Publications

Publication and dissemination plan

Results will be available as of October 2017.

Intention to publish date

01/10/2017

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