A Post-Market, Open Observational Long-term Effectiveness Follow-up Study of Participants with Drug-resistant Epilepsy with Partial-onset Seizures previously Enrolled in a Randomized Controlled Trial (E-100: PuLsE) Comparing Best Medical Practice with or without Adjunctive Vagus Nerve Stimulation Therapy.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26412

Source
Nationaal Trial Register

Brief title
Pulse2

Health condition

refractory epilepsy, Vagus Nerve Stimulation, VNS, NVS, Nervus Vagus Stimulatie, refractaire epilepsie

Sponsors and support

Primary sponsor: Cyberonics Inc
100 Cyberonics Blvd

Houston, Texas 77058
USA
Source(s) of monetary or material Support: Cyberonics Inc
100 Cyberonics Blvd
Houston, Texas 77058
USA

Intervention

Outcome measures

Primary outcome

The objective of this post-market study is to perform exploratory evaluations to identify clinically and statistically significant predictors of response at all follow-up visits in participants with drug-resistant epilepsy with partial-onset seizures treated with Best Medical Practice with or without adjunctive VNS Therapy. This will be accomplished through regression modeling of the response variates (including change in baseline quality of life score and percent reduction in seizure frequency). Predictors will include, but will not be limited to:

1. General demographics: age, gender, ethnicity;

2. Disease-specific demographics such as etiology, age at onset, seizure type;

3. Treatment group (Best Medical Practice without VNS Therapy or Best Medical Practice with adjunctive VNS Therapy);

4. Baseline values of health outcomes (quality of life, seizure frequency, comorbid depression, and adverse event profile).

Secondary outcome

1. To evaluate the change from baseline at all follow-up visits of Best Medical Practice with adjunctive VNS Therapy compared to Best Medical Practice without VNS Therapy in participants with drug-resistant epilepsy with partial-onset seizures as measured by:

A. Response rates (greater than or equal to 50% reduction in seizures compared to baseline) at all follow-up visits;

B. Response rates (greater than or equal to 75% reduction in seizures compared to baseline) at all follow-up visits;

C. Percent of participants that are seizure free for at least one year at all follow-up visits;

D. Mean and median percent change in seizure frequency (in total and by seizure type) at all

follow-up visits;

E. Seizure free days: time from last seizure to study exit date, and seizure free days over the last 3 months.

2. To evaluate the change from baseline at all follow-up visits across all health outcome measurements (including quality of life, seizure frequency, comorbid depression, and adverse event profile) for Best Medical Practice with adjunctive VNS Therapy compared to Best Medical Practice without VNS Therapy;

3. To evaluate the safety and tolerability of Best Medical Practice with adjunctive VNS Therapy using information on treatment emergent adverse events and device complications at all visits;

4. To evaluate the change from baseline at all follow-up visits of Best Medical Practice with and without adjunctive VNS Therapy on health outcome measurements and quality of life (QOL) in participants with drug-resistant epilepsy with partial-onset seizures and less then a 50% reduction in seizures (non-responders);

5. A sub-analysis may be performed to evaluate the change from baseline on quality of life for participants with a baseline Adverse Event Profile (AEP) score less than 40 compared to participants with a baseline AEP score greater than or equal to 40.

Study description

Background summary

N/A

Study objective

N/A

Study design

During screening (Visit 1), inclusion/exclusion criteria will be assessed and both the Investigator and participant will sign and date the informed consent. Each enrolled participant will receive 3 months of daily seizure diaries, which will be used to collect seizure frequency information prior to Visit 2.

Visit 2 will take place at least 3 months after the screening visit and only after 3 consecutive months of seizure diary data have been obtained.

Visits 3, 4 and 5 will take place 3, 4 and 5 years, respectively after the randomization date in

original PuLsE study, where applicable. If the time period between Visit 2 and the next scheduled follow-up visit (3 or 4 years after original randomization date) is less than 6 months, these visits may coincide.

Intervention

Participants who took part in the original PuLsE study and who have baseline data will be contacted by the Investigator to request participation in the follow-up study (PuLsE2). The randomization date in the original PuLsE study will serve as the start of the baseline period for this follow-up study; therefore, baseline data obtained in the original PuLsE study will also serve as baseline for the PuLsE2 study.

This study will have a maximum of 5 visits including a screening visit and 3-4 follow-up visits depending on the original randomization date:

1. Screening (Visit 1): Prospective participants will sign an informed consent and will be screened for inclusion/exclusion criteria. Each participant that meets all inclusion criteria and none of the exclusion criteria will continue with a current evaluation of seizure frequency. Participants will be given daily seizure diaries to complete for the 3 consecutive months prior to Visit 2 to document their seizures and any medication changes. Participants will bring completed seizure diaries to all follow-up visits;

2. Follow-up visits (Visits 2-5): Three months prior to each participant's follow-up visit, the study site will contact the participant as a courtesy to remind the participant to begin completing their daily seizure diary. Each participant will return for follow-up visits at the following time points (as applicable based on the original randomization date): 3 months after the PuLsE2 screening visit, and 3, 4, and 5 years (+/- 3 months) after original randomization date. Depending on the original randomization date, participants may only qualify for 4 and 5 year follow-up visits. Seizure frequency, health outcomes, VNS Therapy programming, concomitant medications, and adverse events will be evaluated at each follow-up visit. The study termination visit will also include neurological and physical examinations.

If Visit 2 (3 months after PuLsE2 screening visit) occurs within 6 months (before or after) of the next scheduled follow-up visit (3 or 4 years after randomization in PuLsE), these visits may coincide.

Contacts

Public
Cyberonics Inc
100 Cyberonics Blvd
Mark Bunker

Houston 77058
The Netherlands
+1 281 2287223
Scientific
Cyberonics Inc
100 Cyberonics Blvd
Mark Bunker
Houston 77058
The Netherlands
+1 281 2287223

Eligibility criteria

Inclusion criteria

To be eligible for the study, the participant must meet all the following criteria:

1. Participant must have been randomized in the original PuLsE study;

2. Participant must have baseline data from the original PuLsE study;

3. Participant is able to give accurate seizure counts, health outcomes information, and complete study instruments with minimal assistance;

4. Participant or legal guardian understands study procedures and has voluntarily signed an informed consent for PuLsE2 in accordance with institutional and local regulatory policies. Participant must sign informed consent within 9 months of submission to the study site’s Ethics Committee.

Exclusion criteria

The presence of any of the following will exclude a participant from the study:

1. Participant has a history of non-compliance with the completion of a seizure diary;

2. Participant currently uses, or is expected to use during the study, short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy;

3. Participant is expected to require full body magnetic resonance imaging during the clinical study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-02-2011
Enrollment:	121
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2659
NTR-old	NTR2787
Other	Cyberonics : E-101
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A