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.

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N/A

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26412

Bron
Nationaal Trial Register

Verkorte titel
Pulse2

Aandoening

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

Ondersteuning

Primaire sponsor: Cyberonics Inc

100 Cyberonics Blvd
Houston, Texas 77058
USA
Overige ondersteuning: Cyberonics Inc
100 Cyberonics Blvd
Houston, Texas 77058
USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-02-2011
Aantal proefpersonen:	121
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A