Augmenting the sensitivity of the epileptic brain to anti-epileptic drugs by applying transcutaneous vagal nerve stimulation that changes the excitability of the cortex and influences network plasticity.

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Determine the priming effect on the epileptic brain of tVNS, to make it more susceptible to treatment with Brivaracetam (BRV), an AED. In addition, we aim to visualize these changes in the brain because of priming, possibly altered network-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON52498

Source
ToetsingOnline

Brief title
Priming the epileptic brain (PREP)

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, falling sickness

Research involving

Human

Sponsors and support

Primary sponsor: Technische Universiteit Eindhoven
Source(s) of monetary or material Support: Academisch Centrum voor Epileptologie Kempenhaeghe,Gecombineerd;zie G3,Hobo Heeze B.V. (dochter onderneming Kempenhaeghe verantwoordelijk voor tak onderzoek),UCB Pharma

Intervention

Keyword: Anticonvulsants, Epilepsy, Priming, Vagus nerve stimulation

Outcome measures

Primary outcome

Scoring on a composite index combining seizure reduction, improvement of

cognition and quality of life.

Secondary outcome

Seizure reduction, seizure freedom rates, seizure severity, cognition, mood

state, adverse events tVNS and brivaracetam, change in brain network properties

Study description

Background summary

The most prevalent neurological disorder with also immense burden of disease, epilepsy, is in over 30 percent of patients difficult to treat. The ideal treatment regime would give complete control of disease in an early stage, not only for patient well-being, but also to prevent the onset of persistent pathologic epileptic networks in the brain. The first step in treatment is the trial, and error, of multiple anti-epileptic drugs (AEDs), while invasive brain stimulation (BS) techniques with network modulating properties are saved as a last resort. We hypothesize that pharmacotherapeutic treatment of epilepsy can be more successful after *priming* (preparing) the brain using BS as a short-term neuromodulation treatment. The limitation of testing this hypothesis is the invasive aspect of the most used classic vagal nerve stimulation (VNS) treatment for epilepsy, but the recent development of transcutaneous vagal nerve stimulation (tVNS) offered a possibility to combine chemical and

electrical modulation in an earlier stage of disease, which is not tested before.

Study objective

Determine the priming effect on the epileptic brain of tVNS, to make it more susceptible to treatment with Brivaracetam (BRV), an AED. In addition, we aim to visualize these changes in the brain because of priming, possibly altered network-organisation.

Study design

Pretest-posttest study

Intervention

The group receives transcutaneous vagal nerve stimulation (tVNS) 4 hours daily during brivaracetam treatment.

Study burden and risks

Besides minor temporary side effects no risk is attributed to tVNS. Because of the study one extra visit is necessary, besides regular clinical follow-up. The 3 visits do require some more time than usual because of the questionnaires, MRI and short cognitive tests.

The burden of the telephone calls is very limited, since it only consists of a few short questions.

Patients with claustrophobia are excluded, but the requirement of lying still can be somewhat uncomfortable.

The eye tracking device uses a camera in the video screen, with no burden at all.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

focal epilepsy, refractory to treatment after at least 2 different adequatly dosed anti-epileptic drugs, >17 years of age, IQ>70

Exclusion criteria

Other progressive central neurologic disease in history, inability to give informed consent, contra-indication for MRI or tVNS, already treatment with brain stimulation, incapable of handling tVNS device, known cardiac arrhythmia

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-08-2022
Enrollment:	23
Type:	Actual

Medical products/devices used

Generic name:	transcutaneous vagal nerve stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-08-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-10-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-05-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-04-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-04-2024
Application type:	Amendment

Review commission: METC Maxima Medisch Centrum (Veldhoven)

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
ClinicalTrials.gov	NCT05180916
CCMO	NL73868.015.20