QUality of life and Economic evaluation after neuroSTimulation for Epilepsy

No registrations found.

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

Summary

ID

NL-OMON26320

Source
NTR

Brief title
QUESTE

Health condition

Epilepsy

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Disease specific quality of life

Secondary outcome

General quality of life, seizure frequency, care use, productivity

Study description

Background summary

Epilepsy is one of the most common neurological disorders and is characterised by seizures. Epilepsy is associated with a decrease in quality of life. The standard treatment for epilepsy is the use of anti-epileptic drugs. In around 40% of patients these drugs do not achieve adequate results, which makes these patients refractory epilepsy patients. Refractory epilepsy patients are considered for resective epilepsy surgery, an intended curative treatment where the epileptical focus in the brain is surgically removed. If resective surgery is not possible or did not work, the use of neuromodulation (DBS or VNS) can be considered. Where resective surgery is aimed to result in a 100% seizure reduction, prior research shows that DBS leads to an average seizure reduction of 56% after two years and VNS leads to an average seizure reduction of 30,9% after 14 weeks. In order to look at the cost-effectiveness of ANT DBS and VNS for refractory epilepsy patients, it is valuable to look at how quality of life in these patients changes after their treatment.

Study objective

Hypothesis 1: Refractory epilepsy patients will report a significant increase in quality of life, one and two years after ANT DBS or VNS treatment.

Hypothesis 2: Refractory epilepsy patients will report a significant seizure frequency reduction and a significant seizure severity reduction, one and two years after ANT DBS or VNS treatment.

Hypothesis 3: Refractory epilepsy patients will report a significant decrease in the amount of care use, one and two years after ANT DBS or VNS.

Hypothesis 4: Refractory epilepsy patients will report a significant increase in productivity, one and two years after ANT DBS or VNS treatment.

Hypothesis 5: Refractory epilepsy patients who choose to replace their stimulators battery, will report a significant higher quality of life compared to patients who choose to not replace their stimulators battery.

Study design

Baseline, 6 months, 12 months, 24 months, 60 months

Intervention

QOLIE-31, EQ-5D-5L standard version and proxy version 2, iMCQ (iMTA Medical Costs Questionnaire), iPCQ (iMTA Productivity Costs Questionnaire), IDQOL-16

Contacts

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Eligibility criteria

Inclusion criteria

Medically refractory epilepsy patients indicated for ANT DBS or VNS from january 2021 until january 2026 that will take place in Maastricht UMC+, Amsterdam UMC (location AMC) and Medisch Spectrum Twente.

Exclusion criteria

Patients without a Dutch language proficiency or with a total IQ score lower than 50.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-01-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL9033
Other	METC MUMC+ : 2020-2439

Study results