

Resective Epilepsy Surgery, Quality of life and Economic evaluation.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21022

Bron

NTR

Verkorte titel

RESQUE

Aandoening

Epilepsy

Ondersteuning

Primaire sponsor: not applicable

Overige ondersteuning: no funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is change in disease specific quality of life (expressed in points change at the QOLIE-31 questionnaire).

Toelichting onderzoek

Achtergrond van het onderzoek

Epilepsy is one of the most common neurological diseases and is characterized by epileptic seizures. An epileptic seizure is an episodic event that is caused by excessive paroxysmal electric discharges of brain cells. Epilepsy is associated with a diminished quality of life. The standard treatment is with anti-epileptic drugs. About 40% of the patients does not achieve satisfying results with anti-epileptic drugs, they suffer from drug-resistant epilepsy. For some of these patients resective epilepsy surgery, where the part of the brain where the abnormal discharging brain cells are located, is surgically removed, can be an effective treatment, resulting in seizure freedom or significant reduction of seizure frequency. Seizure reduction is one of the most important determinants of quality of life for epilepsy patients.

The objective of the RESQUE-study is to evaluate the change in quality of life of drug-resistant epilepsy patients during 2 years after epilepsy surgery. Also, data with respect to seizure frequency, seizure severity, side effects, use of medical care (anti-epileptic drugs, number of visits to the emergency department, neurology consults, hospital admittance) and productivity (ability to work, social functioning) will be collected. The data will be used to conduct an economic evaluation of resective epilepsy surgery.

Doel van het onderzoek

The hypothesis is that drug-resistant epilepsy patients will report a significant increase in quality of life 1 and 2 years after resective epilepsy surgery. The study is a prospective cohort study. The study population consists of adult drug-resistant epilepsy patients that receive resective epilepsy surgery in the Maastricht UMC+ and the Amsterdam UMC (location VU) in the period of September 2020 until September 2021. Patients will fill out validated questionnaires on baseline and 3-6-12-24 months after surgery.

Onderzoeksopzet

inclusion 01-09-2020

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Included will be patients that are selected for surgery between September 2019 and September 2021 in the Maastricht UMC+ and Amsterdam UMC.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Excluded will be patients who do not speak Dutch or patients who are considered mentally deficient (TIQ below 70), because they are expected not to be able to fill out the questionnaires. With a disharmonic level of intelligence the verbal IQ (<70) is leading.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart

(Verwachte) startdatum: 01-09-2019
Aantal proefpersonen: 100
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 08-01-2020
Soort: Eerste indiening

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	NL8278
Ander register	METC MUMC+ : METC 2019-1134

Resultaten