

# Resective Epilepsy Surgery, Quality of life and Economic evaluation.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21022

### Source

NTR

### Brief title

RESQUE

### Health condition

Epilepsy

## Sponsors and support

**Primary sponsor:** not applicable

**Source(s) of monetary or material Support:** no funding

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

Secondary outcomes are change in general quality of life (expressed in points change at the EQ-5D questionnaire), seizure frequency (ILAE-classification), use of care (iMCQ), productivity (iPCQ), the correlation between change in quality of life and seizure reduction. Also, based on these outcomes, an economic evaluation will be performed.

## Study description

### Background summary

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.

### Study objective

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.

### Study design

inclusion 01-09-2020

## Contacts

### Public

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

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

### **Exclusion criteria**

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.

## **Study design**

### **Design**

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### **Recruitment**

NL

Recruitment status: Recruiting

Start date (anticipated):	01-09-2019
Enrollment:	100
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	08-01-2020
Application type:	First submission

## 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	NL8278
Other	METC MUMC+ : METC 2019-1134

## Study results