# Effects of radiofrequency thermoCOagulation on brain NeTwork ACTivity in patients with epilepsy (CONTACT-study)

Published: 03-04-2023 Last updated: 06-04-2024

The research objective is to obtain a more targeted RFTC treatment strategy by gaining more insight into the organization of epilepsy networks. We will study how RFTC affects large-scale brain networks in focal epilepsy and whether these network...

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

# Summary

### ID

NL-OMON53677

**Source** ToetsingOnline

Brief title CONTACT-study

# Condition

Seizures (incl subtypes)

**Synonym** convulsions, Epilepsy, Seizures

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Neurochirurgie

1 - Effects of radiofrequency thermoCOagulation on brain NeTwork ACTivity in patient ... 3-05-2025

Source(s) of monetary or material Support: Subsidie aanvraag loopt bij EpilepsieNL

### Intervention

Keyword: Epilepsy, MRI, Radiofrequency thermocoagulation, Stereo-electroencephalography

### **Outcome measures**

#### **Primary outcome**

The primary endpoint is the post-treatment seizure outcome

(ILAE-classification)26 at 12 months post-RFTC.

Interim measurements include seizure outcome at 3 and 6 months post-RFTC.

Seizure outcome is determined by the treating physician at set interval at the

outpatient clinic.

### Secondary outcome

Secondary endpoints will be (in order of secondary research questions):

- 1. Same as primary/main parameter/endpoint
- 2. SEEG findings comprising baseline recordings, seizure recordings,

stimulations at 1 Hz pre- and post-RFTC. Data is recorded during the inpatient

admission by the treating physician.

3. Neurological outcomes between 6 to 12 months post-RFTC determined by the

treating physician through neurological examination and neuropsychological

outcomes between 6 to 12 months by using standardized tests.

# **Study description**

### **Background summary**

Epilepsy, the fourth most common chronic brain disorder, is characterized by recurrent seizures. In focal epilepsy, the seizures start at a specific place

2 - Effects of radiofrequency thermoCOagulation on brain NeTwork ACTivity in patient ... 3-05-2025

in the brain: the epileptogenic zone. Brain surgery, in which the epileptogenic zone is removed, can stop or reduce seizures in selected patients who have not been helped with anti-epileptic drugs. Several non-invasive investigations are required to determine the location of the epileptogenic zone. If these are insufficiently certain to demonstrate the epileptogenic zone, an invasive brain examination, such as stereo-electroencephalography (SEEG), may be the answer. In this SEEG study, multiple depth electrodes are implanted in the brain, followed by a seizure registration to determine the epileptogenic zone.

In addition to removing this epileptogenic zone through brain surgery, minimally invasive treatment methods have recently become available. One of these is SEEG-guided radiofrequency thermocoagulation (RFTC), which turns a seizure diagnostic technique (SEEG) into a technique to treat these seizures during the same study. The epileptogenic zone is locally heated and destroyed by a short-term application of current via the implanted SEEG electrodes. RFTC is a treatment method with a chance of cure in patients who are either not eligible for brain surgery (neurosurgical inaccessible areas of the brain) or as a precursor to later brain surgery if the epileptogenic zone is not yet completely clear. With (temporary) seizure reduction after RFTC, a good outcome can be expected after eventual epilepsy surgery. RFTC thus offers a cure for patients who can only expect relief from seizures with non-curative treatments.

In recent years, it has been increasingly assumed that focal epilepsy is not limited to a single epilepsy source, but rather a widespread epilepsy network: a group of brain regions whose activity in one site will affect activity in all others. This new way of thinking about focal epilepsy has implications for the surgical approach. Interrupting a critical network node will affect the seizures. The subject of modern research is to determine critical brain nodes within the epilepsy network.

### **Study objective**

The research objective is to obtain a more targeted RFTC treatment strategy by gaining more insight into the organization of epilepsy networks. We will study how RFTC affects large-scale brain networks in focal epilepsy and whether these network changes relate to treatment effect and/or neuro(psycho)logical outcome. We will also investigate whether electrophysiological and neuroimaging network biomarkers can predict treatment outcome prior to RFTC. With this we want to be able to better identify the optimal target for RFTC. The aim is to improve treatment options with seizure freedom without neuro(psycho)logical deficits.

### Study design

Study design: This study is a prospective, longitudinal, observational cohort study.

Duration: Total duration of the study will be 4 years. Study duration

compromises 1) an inclusion phase with collection of data (duration 2,75 years) with at least one year follow-up for each patient and 2) an analysis phase with data analysis and reporting (duration 4 years), starting in parallel with the inclusion phase. Research will be conducted according to all GCP standards.

#### Study burden and risks

- When participating in this study, additional brain MRI sequences will be performed on the patient during the study. This is done during two outpatient MRI examinations (without SEEG electrodes) that are scheduled as part of the regular treatment. As a result, the patient will have to stay in the MRI scanner twice for approximately 30 minutes longer (each MRI examination will not take longer than 60 minutes).

- There is no additional (day) admission or administration of drugs specifically for this study.

During the research period, admissions will be made - completely within the framework of regular care - at the Academic Center for Epileptology Kempenhaeghe and Maastricht UMC+ for 1/ surgical implantation of the SEEG electrodes (admission MUMC+), 2/ SEEG seizure registration and radiofrequency thermocoagulation ( admission Kempenhaeghe OR MUMC+) and 3/ surgical explantation of the SEEG electrodes (admission MUMC+).

- The patient does not have to carry out any assignments specific to the study at home.

- No drugs are administered specifically for this study.

# Contacts

**Public** Selecteer

P. Debyelaan 25 Maastricht 6229HX NL **Scientific** Selecteer

P. Debyelaan 25 Maastricht 6229HX NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

patients (age >=18 years) with DRE under presurgical evaluation for epilepsy surgery through SEEG potentially eligible for RFTC treatment patients able to give informed consent

### **Exclusion criteria**

-Patients who cannot meet the mild physical or psychological criteria for prolonged MRI recording -Pacemaker, VNS, DBS, and other MRI incompatible metal implants -Pregnancy

# Study design

### Design

Study type: Observational invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-08-2023
Enrollment:	90

5 - Effects of radiofrequency thermoCOagulation on brain NeTwork ACTivity in patient ... 3-05-2025

Type:

#### Actual

Ethics review	
Approved WMO Date:	03-04-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

# **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** CCMO

ID NL80927.068.22