Localized epilepsy and neural networks.

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

Samenvatting

ID

NL-OMON21379

Bron
NTR

Verkorte titel
LESION

Aandoening

Epilepsy
Lesion
Brain tumor
Low grade glioma
Mesiotemporal sclerosis
MTS

Ondersteuning

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Overige ondersteuning: Netherlands Epilepsy Foundation (NEF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters are a ECoG and MEG-based measures, assessing functional connectivity (SL and PLI) and neuronal brain networks (cluster coefficient and path length), seizure frequency and epilepsy burden.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Epilepsy is common in patients with circumscribed brain abnormalities, such as primary brain tumours and focal cortical dysplasias. In a substantial number of these patients, anti-epileptic drug treatment is ineffective. Patients with lesional epilepsy in whom no brain tumour is present will be referred to epilepsy surgery programs. The aim of these programs is to (1)

identify and, subsequently, (2) remove the ictal zone. This leads to long-term seizure freedom in only 30-60% of patients.
Although in patients with brain tumours the primary aim of surgery is the removal of the tumour, it is increasingly acknowledged that resective surgery may also result in a decrease of seizure frequency. For both patient groups, improvement of outcome of epilepsy surgery will therefore be extremely relevant.

Electrocorticography (ECoG) and magnetoencephalography (MEG) are imaging techniques that are used for detection of seizure activity and epileptic source localization as well as assessment of functional connectivity and neural network features throughout the brain. Recent research advances concerning functional connectivity and network properties of the brain have indicated that these techniques may be used for epileptic source localization and to investigate factors that determine the frequency of epileptic seizures. Application of these methods in candidates for epilepsy surgery may lead to more effective treatment and improvement of surgical outcome.

Objective:
The primary objective of this study is to characterize functional brain networks in patients considered for (i) epilepsy surgery and (ii) tumour surgery with epilepsy surgery techniques. Characterization will be done preoperatively (MEG), during surgery (ECoG) and post surgery (MEG). At each stage, networks will be characterized using graph theoretical measures that are expected to be related to seizure proneness.

The secondary objectives of this study are:
(1) To relate network properties at different stages to (i) seizure frequency, (ii) seizure burden, and (iii) cognition; (2) To develop a model to predict the effect of surgery on network changes and reduction of seizure burden.

Study design:
This is a longitudinal observational study.

Study population:
40 Adult (≥18 years), pharmacoresistant epilepsy patients who undergo epilepsy surgery, and adult brain tumour patients with epilepsy who undergo tumour surgery with epilepsy surgery techniques.

Main study parameters/endpoints:
The main study parameters are ECoG and MEG measures assessing functional connectivity and neuronal brain networks (clustering coefficient and path length), as well as the clinical measures of seizure frequency, epilepsy burden and cognition.

Doel van het onderzoek

Better guided resection of brain areas that are, regarding network characteristics, important for seizure onset and propagation may result in improved clinical outcome. However, before such guidance is possible, more insight into the effects of resective surgery on functional network characteristics, and on clinical outcome, is required. In order to do this, we propose

the development of a computational model that predicts the impact of resective surgery on neural networks. Furthermore, we plan to study the correlation between network characteristics, based on MEG and ECoG recordings, and surgical outcome, in terms of epilepsy frequency, epilepsy burden and cognition.

Onderzoeksopzet

1. Pre-resection;

2. 3 months post-resection;

3. 9 months post-resection.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for pharmacoresistant epilepsy patients are:

1. Adult (≥ 18 years);

2. Patients who undergo resective surgical treatment at the VUmc regarding the Dutch Collaborative Epilepsy Surgery Program;

3. Have given written informed consent.

For brain tumour patients with epilepsy, inclusion criteria are:

1. Adult (≥ 18 years);

2. Patients who undergo resective surgical treatment of the tumour with epilepsy surgery techniques at the VUmc;

3. Are suffering from epilepsy which was not pre-existent to the lesion;

4. Have given written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are:

1. Psychiatric disease or symptoms;

2. Insufficient mastery of the Dutch language;

3. Inability to communicate adequately.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-07-2009
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-07-2009
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	NL1785

Register	ID
NTR-old	NTR1895
Ander register	Netherlands Epilepsy Foundation : NEF0909
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A