Localized epilepsy and neural networks.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21379

Source
NTR

Brief title
LESION

Health condition

Epilepsy
Lesion
Brain tumor
Low grade glioma
Mesiotemporal sclerosis
MTS

Sponsors and support

Primary sponsor: Dr J.C. Reijneveld, neurologist
Department of Neurology - ZH 2F.35
VU University Medical Center
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4442821
F +31 20 4442800
Email: JC.Reijneveld@vumc.nl

Prof dr C.J. Stam, neurologist/neurophysiologist
Department of Clinical Neurophysiology – PK -1Z.142

VU University Medical Centre
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4440677
Email: CJ.Stam@vumc.nl

Drs. H.E. Ronner, neurophysiologist
Department of Clinical Neurophysiology – PK -1Z.148
VU University Medical Centre
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4440730

Drs J.C. Baayen
Department of Neurosurgery – ZH 2F-004
VU University Medical Center
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4440807
Email: JC.Baayen@vumc.nl

P.C. De Witt Hamer
Department of Neurosurgery – ZH 2F-010
VU Medical Center
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4443714
Email: P.DeWittHamer@vumc.nl

Drs L. Douw
Department of Neurology - ZH 1F.005
VU University Medical Center
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4446027
Email: L.Douw@vumc.nl

M. Klein, PhD
Department of Medical Psychology - D349
VU University Medical Center
Van der Boechorststraat 7
1081 BT Amsterdam

The Netherlands
T +31 20 4448432

D.N. Velis
Department of Clinical Neurophysiology
SEIN Epilepsy Center Meer en Bosch
2103 SW Heemstede
The Netherlands
T +31 235 588175
Email: dnv@sein.nl

E. van Dellen
Department of Neurology - ZH 1F.005
VU University Medical Center
PO Box 7057
1007 MB Amsterdam
The Netherlands
T +31 20 4444234
Email: E.vanDellen@vumc.nl

Source(s) of monetary or material Support: Netherlands Epilepsy Foundation (NEF)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

1. Pre-resection;

2. 3 months post-resection;

3. 9 months post-resection.

Intervention

N/A

Contacts

Public
Postbus 7057
E. Dellen, van
Department of Neurology - ZH 1F.003/005
VU Medisch Centrum

Amsterdam 1007 MB
The Netherlands
+31 (0)20-4444234
Scientific
Postbus 7057
E. Dellen, van
Department of Neurology - ZH 1F.003/005
VU Medisch Centrum

Amsterdam 1007 MB
The Netherlands
+31 (0)20-4444234

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

Exclusion criteria are:

1. Psychiatric disease or symptoms;

2. Insufficient mastery of the Dutch language;

3. Inability to communicate adequately.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-07-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-07-2009
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	NL1785
NTR-old	NTR1895
Other	Netherlands Epilepsy Foundation : NEF0909
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A