Characterisation of neurotransmitter network dysfunction in MRI-negative localisation-related epilepsy

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To compare the neurotransmitter networks of patients with localisation-related epilepsy patients to those of healthy subjects; To explore the relationship between neurotransmitter, functional and structural network properties, and relate these to...

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

Summary

ID

NL-OMON40961

Source
ToetsingOnline

Brief title
Neurotransmitter network dysfunction in epilepsy

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy, falling sickness

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: epilepsy, graph theoretical analysis, MRSI, neurotransmitter networks

Outcome measures

Primary outcome

The primary study parameters are the neurotransmitter network properties of MRI-negative localization-related epilepsy patients compared to those of healthy subjects.

Secondary outcome

Secondary study parameters are functional and structural network properties and the relation between these and the neurotransmitter network properties of MRI-negative localisation-related epilepsy patients.

Study description

Background summary

A large portion of patients with intractable epilepsy does not become completely seizure free after resection of the epileptic focus in epilepsy. This ineffectiveness might be due to the fact that epilepsy is not necessarily a purely focal disease, but rather is associated with widespread network alterations in the brain, for which deficient functional and structural networks have previously been shown in epilepsy patients. However, these networks do not provide direct information on the defective neurons or the linked neurotransmitter disbalance. We propose the novel application of graph theoretical analysis in magnetic resonance spectroscopic imaging, to provide insight into the neurotransmitter network dysfunction in MRI*negative epilepsy. This will be of great value to eventually better understand the neuronal network characteristics of epilepsy and potentially the underlying mechanism of surgical failure in epilepsy.

Study objective

To compare the neurotransmitter networks of patients with localisation-related epilepsy patients to those of healthy subjects; To explore the relationship

between neurotransmitter, functional and structural network properties, and relate these to clinical characteristics.

Study design

This is an observational study comparing epilepsy patients with healthy subjects. MRI measures of MRI-negative localization-related epilepsy patients will be compared to those of healthy subjects, matched for age and gender. Each subject will undergo MRI measurements at one time point.

Study burden and risks

The subjects will undergo one MR scanning session (about 1 hour in duration) at a 7T MRI scanner. The patient group might benefit from this scan, because occasionally structural lesions can be found at 7T that were not found at the clinical scans at 3T, and thereby improving the possibilities for epilepsy surgery. However, we argue that this has a small chance. The risks for the subjects participating in this study are minimal. A small amount of people may experience vertigo or nausea while entering the scanner, but not during the scan itself. Also a smaller amount of people may experience a metallic taste in their mouth during the scan.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General:
Subjects must be older than 18 years and able to give informed consent. ;Epilepsy patients:
- Diagnosed with cryptogenic localization-related epilepsy with an epileptic focus in the frontal or temporal lobe (using EEG)
- Seizure frequency below 13/year.
- No changes in anti-epileptic drugs (medication or dose) in the last 6 months.

Exclusion criteria

General:
- MRI visible lesions, as seen on the clinical 3T scans
- All absolute or relative contraindications for MR scanning.
- A medical history with cerebral diseases (other than epilepsy), vascular problems, diabetes mellitus, hypertension and/or cerebral surgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	21-11-2014
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	03-11-2014
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	ID
CCMO	NL50613.068.14

Study results

Date completed:	15-11-2016
Actual enrolment:	24