LADYS study.

Gepubliceerd: 05-05-2010 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON27600

Bron
NTR

Verkorte titel
LADYS study

Aandoening

epilepsy
focal cortical dysplasia
MRI
connectivity

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Epilepsy Center Kempenhaeghe
Overige ondersteuning: Dutch Epilepsy Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

For DTI the quantitative outcome parameters will be the local apparent diffusion coefficient (ADC), fractional anisotropy (FA), and tract volume and tract FA values seeded in the white matter region close to the BOSD. These parameters will be obtained in the region close to the BOSD and the corresponding contralateral (normal) regions.
For rs-fMRI the correlation coefficient will be determined between the rs-fMRI time course signal from a region in the BOSD and all voxels in the rest of the brain. The resulting map will be compared with the same analysis seeded to the contralateral region. Besides the time courses, also the spectrum (Fourier transformed signal) of the time courses will be analyzed. For this the amplitudes of the spectral components in the high (> 80 mHz) and low (<80 mHz) frequency ranges will be compared between the BOSD region and the contralateral region.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Epilepsy is one of the common neurologic syndromes with a lifetime incidence of 2-4% and about 50% of these patients suffer from partial seizures. Neuroimaging is used to determine the origin of these seizures. However, in up to 74% of these patients with location related (partial) seizures, MRI shows no abnormalities. It is assumed that the majority of these patients have a small cortical dysplasia. Detecting these lesions is of clinical importance because in patients with intractable epilepsy, as resection of the focal cortical dysplasia may be the only viable therapeutic option and there is an excellent prognosis for seizure control following focal resection.

Objective:

The goal is to achieve a more sensitive method for detecting malformations of cortical development. The main hypothesis in the current study is that focal cortical dysplasias have abnormal connections. Therefore we aim to characterize the functional and structural connectivity of a specific type of focal cortical dysplasia.

Study design:

Cohort Study.

Study population:

Twenty patients with localization-related seizures and the diagnosis of BOSD on conventional MRI and twenty matched healthy volunteers.

Main study parameters/endpoints:

The outcome parameters will be the local apparent diffusion coefficient (ADC), fractional anisotropy (FA), tract volume and tract FA and the correlation coefficient between the resting state fMRI time course signal from a region in the BOSD and all voxels in the rest of the brain. The resulting map will be compared with the same analysis seeded to the contralateral region.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The MRI-techniques and questionnaire that are used in this study are non-invasive. The risks of a MRI-scan are negligible because it is a magnetic field, does not involve ionizing radiation and does not require contrast agents or anesthesia. The education questionnaire will take less than 10 minutes.

Doel van het onderzoek

The goal is to achieve a more sensitive method for detecting malformations of cortical development. The main hypothesis in the current study is that focal cortical dysplasias have abnormal connections. Therefore we aim to characterize the functional and structural connectivity of a specific type of focal cortical dysplasia.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients:

Legally capable adults with and the diagnosis of localization-related seizures and a BOSD on a state-of-the art 3 Tesla MRI. Based on the seizure semiology and EEG the BOSD must be most likely epileptogenic focus. In our files we have over 50 patients who fulfill the inclusion criteria for this study.

Normal volunteers:

Legally capable adult volunteers without a serious medical problem and no medical history of head trauma or other neurological or psychiatric diseases.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contra indications for MRI.

For the normal volunteers:

1. Medical history of head trauma or other neurological or psychiatric disease;

2. The expressed wish not to be informed whenever structural abnormalities are found during imaging.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2010
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-05-2010
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	NL2191
NTR-old	NTR2315
Ander register	Dutch Epilepsy Foundation : NEF10-08
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A