IMAGINE-Study (Imaging in Epilepsy) Onderzoek naar de oorzaak van geheugenproblemen en falen van medicamenteuze behandeling bij kinderen met frontaalkwab epilepsie.

Gepubliceerd: 07-04-2009 Laatst bijgewerkt: 18-08-2022

Based on the type of cognitive impairments frequently observed in children with frontal lobe epilepsy, functional networks in the frontal and/or temporal lobe are expected to be disrupted. Therefore we expect neuronal reorganisation especially in...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28826

Bron
Nationaal Trial Register

Verkorte titel
IMAGINE-study

Aandoening

Frontal lobe epilepsy (FLE), i.e. epilepsy with a frontal epileptic focus, represents a substantial proportion of all partial epilepsies. The average age at onset of FLE is between 6 and 12 years. After the diagnosis FLE is made, the prognosis is still uncertain. Part of the children responds well to antiepileptic drug (AED) treatment, while others will become refractory and have frequent and disabling seizures. A second problem is that part of the children with FLE will suffer from cognitive impairment. The nature and severity of this impairment is highly variable, but it may seriously affect their development. Up to now, no clear patient or epilepsy-related factors responsible for refractoriness and/or cognitive decline have been identified, and structural MRI scans commonly reveal no abnormalities that may explain this, even after years of ongoing seizures. Therefore, there are no markers to recognise this patient category.

Ondersteuning

Primaire sponsor: Epilepsy Center Kempenhaeghe
Overige ondersteuning: Epilepsy Center Kempenhaeghe

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Macrostructural, microstructural and functional MRI parameters, combined with seizure history, IQ, and response to anti-epileptic drug treatment. The endpoints for the fMRI tasks are activation levels of different brain areas and the correlation between the time signals between these activated brain areas. This will be analysed pixel by pixel with an automatized computer analysis (SPM software). Herewith, we obtain a list of activation levels and correlation coefficients for every brain region for every patient and every healthy control. Hereafter, these data can, for every task, be statistically compared between patients and healthy controls. This is a standardized and well applied way of data analysis. Endpoints therefore include the activated brain regions and the level of interaction between these regions. This will be processed in terms of:
1. Correlation between fMRI results and neuropsychological test results, and;
2. Differences between patients and healthy controls.

Toelichting onderzoek

Achtergrond van het onderzoek

Frontal lobe epilepsy, i.e. epilepsy with a frontal epileptic focus, represents a substantial proportion of all partial epilepsies. The average age at onset of frontal lobe epilepsy is between 6 and 12 years. After the diagnosis is made, the prognosis is still uncertain. Part of the children responds well to antiepileptic drug treatment, while others will become refractory and have frequent and disabling seizures. A second problem is that part of the children with frontal lobe epilepsy will suffer from cognitive impairment. The nature and severity of this impairment is highly variable, but it may seriously affect their development. Up to now, no clear patient or epilepsy-related factors responsible for refractoriness and/or cognitive decline have been identified, and structural MRI scans commonly reveal no abnormalities that may explain this, even after years of ongoing seizures. Therefore, there are no markers to recognise this patient category.In this study we investigate correlations between cognitive impairment as well as response to anti-epileptic drug treatment in children with frontal lobe epilepsy and brain microstructure, function and neuronal connectivity, by using DTI, task related fMRI, and resting state fMRI.

Doel van het onderzoek

Based on the type of cognitive impairments frequently observed in children with frontal lobe epilepsy, functional networks in the frontal and/or temporal lobe are expected to be disrupted. Therefore we expect neuronal reorganisation especially in this early phase of the epilepsy (age 8-12 years), as this is the phase in which refractoriness and cognitive impairment develop. Recently, more advanced MRI-techniques, including diffusion tensor imaging (DTI) and functional magnetic resonance imaging (fMRI) became available. These techniques are capable of visualizing and assessing the level and integrity of functional networks. Such techniques may reveal the neuronal correlates of cognitive impairment and refractoriness on the level of microstructural and functional abnormalities.

Onderzoeksopzet

1. Year 1: Calibration study and image data analysis of the calibration study. After analysis, inclusion and imaging of the first patients and healthy control children for the cohort study. End point: results of healthy adult volunteers from the calibration study;

2. Year 2: Inclusion and imaging of patients and healthy control children for the cohort study. Data analysis;

3. Year 3: Last year for patient inclusion and image data analysis. End point: comparison of results of healthy control children with patients and writing of first manuscripts;

4. Year 4: Further analysis and writing publications and PhD thesis.

Onderzoeksproduct en/of interventie

1. All eligible children diagnosed with FLE will get a structural brain MRI scan, as well as a DTI, resting state fMRI and task related fMRI scan. Neuropsychological assessment will only be repeated if the last test was performed more than one year earlier;

2. Children of the healthy control group (matched for age) will get a neuropsychological assessment. Additionally, a structural MRI scan, as well as a DTI, resting state fMRI and task related fMRI scan will be performed.

Contactpersonen

Publiek

H. Braakman
P. Debyelaan 25
Maastricht 6202 AZ

The Netherlands
+31 ()043 3877056

Wetenschappelijk

H. Braakman
P. Debyelaan 25
Maastricht 6202 AZ
The Netherlands
+31 ()043 3877056

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for children with FLE:

1. Age of 8 to12 years;

2. Clinical and electroencephalographic evidence of seizures originating from the frontal lobe. When EEG is not informative, the recording of more than one seizure with clinical evidence of seizures originating from the frontal lobe is required to make the diagnosis;

3. Non-symptomatic epilepsy.

Inclusion criteria for healthy control children:

1. Children aged 8 to 12 years;

2. Normal intelligence/following regular schools.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for children with FLE:

1. Multiple seizure foci involving more than one lobe of the brain documented on previous EEG studies;

2. Frontal lobe seizures thought to be a result of spread to the frontal lobes;

3. MRI lesions on previous structural brain MRI- or CT-scans or symptomatic epilepsy (e.g. tumours, vascular abnormalities, congenital dysgenesia);

4. Full scale IQ<70 on the Wechsler Intelligence Scale for Children-Third Edition (Wechsler 1991);

5. Progressive neurological disorders;

6. Other diseases/ causes that may underlie cognitive impairment (i.e. psychiatric diseases);

7. Inability to speak/understand the Dutch language;

8. Cognitive deterioration directly after starting with AED, or treatment with Topiramate or Phenobarbital;

9. Vision less than +4.5D or – 4.5D;

10. Claustrophobia;

11. Metal implants or other contraindication for MRI;

12. Parents not willing to provide informed consent.

Exclusion criteria for the healthy control children:

1. Medical history of head trauma or other diseases/ causes that may underlie cognitive impairment (i.e. psychiatric diseases);

2. Inability to speak/understand the Dutch language;

3. Vision less than +4.5D or – 4.5D;

4. Claustrophobia;

5. Metal implants or other contraindication for MRI;

6. Parents not willing to provide informed consent;

7. Parents who do not want to get informed whenever structural abnormalities are found during imaging.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-11-2008
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-04-2009
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	NL1651
NTR-old	NTR1749
Ander register	MEC : 08-3-084
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A