The Rolandic epilepsy/ESES/Landau-Kleffner Syndrome and correlation with Language impairment study

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Identification of a diseased neuronal network characteristic in children with nocturnal epileptiform activity, which can explain language impairment in these children

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

Summary

ID

NL-OMON36427

Source
ToetsingOnline

Brief title
REL&language1

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: epilepsy, impairment, language, nocturnal

Outcome measures

Primary outcome

Abnormalities that are related to Rolandic epilepsy, ESES-like, ESES, LKS, language impairment, cognitive impairment and/or refractoriness. Endpoints are the microstructural and functional integrity, seizure history, IQ-scores, and response to anti-epileptic drug treatment or other treatment (corticosteroids), EEG-parameters (localisation and frequency of epileptic activity). (For further information see: Methods, primary study parameters/endpoints)

Secondary outcome

nvt

Study description

Background summary

In clinical practice language impairment is frequently reported in association with nocturnal epileptiform activity. There is a spectrum of epileptic conditions that are characterized by nocturnal epileptiform activity: Rolandic epilepsy, nocturnal frontal lobe epilepsy, Landau-Kleffner syndrome and electrical status epilepticus of sleep. The exact characteristic of the relationship between nocturnal epileptiform activity and language impairment is yet to explore. We suggest that nocturnal epileptiform EEG discharges and nocturnal epileptic seizures during development will cause diseased neuronal networks that involve language. The diseased neuronal networks are less efficient compared with normal neuronal networks.

Study objective

Identification of a diseased neuronal network characteristic in children with nocturnal epileptiform activity, which can explain language impairment in these

children

Study design

An observational and clinical comparative case-control study, in children with nocturnal epileptiform activity and healthy controls. About 25 children diagnosed with Rolandic epilepsy, LKS, ESES-like ESES will be investigated. 20 healthy matched control children will be tested. Group differences in neuronal network architecture will be examined, and the MR parameters will be correlated to the language impairment.
EEG-parameters will be correlated to MR and language impairment.

Study burden and risks

This study involves minors who are unable to give informed consent. Following the WMO guidelines, the *not unless* principle applies to granting permission for this study. The MRI-techniques and neuropsychological assessments that are applied in this study are non-invasive. We use a 3.0 Tesla MRI instead of a 1.5 Tesla MRI. 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 anaesthetics. The brain imaging will be more detailed by using a 3.0 Tesla MRI compared with a 1.5 Tesla MRI. Another reason why we use 3.0 Tesla MRI instead of 1.5 Tesla MRI is that a 1.5 Tesla MRI is not available at the epilepsy centre Kempenhaeghe. Furthermore, according to the literature, there are no statistically significant difference between 1.5 Tesla MRI and 4.0 Tesla MRI for headache, tinnitus, hiccupping, vomiting and numbness. The difference is not known for 1.5 and 3.0 Tesla MRI, but it is assumable that this difference is also not statistically significant for less stronger magnetic field.To minimize the burden, we will start with good education, including an information folder. Children can get used to the sound of the MRI-scan from a computer program. Children will be constantly guided by their parents and a specialized trial nurse. The scanning environment will be made as comfortable and cosy as possible. A Walt Disney movie will be displayed between the scanning sessions. In preparation, the children will be familiarized with the MRI system. The scanning time is 2 times 30 minutes with a half hour break in between (if necessary longer) and consists of individual programs with an average duration of 7 minutes. These sessions can be interrupted at any time, and children are allowed to break up or stop the scanning and leave the MRI room at any time. The neuropsychological assessment will take one hour in total. Moreover, we will apply short scan protocols to minimize the magnet time of all the children.

The 24 hour EEG is carried by the child for 24 hour (electrodes and battery). This will only be performed in patients, electively. The patient cannot shower/bathe during the examination.

Recruitment of children in the age of 8-18 years is essential as Rolandic epilepsy, ESES, ESES-like and LKS are basically diseases of childhood and often disappears during adolescence (commonly with persistence of the cognitive impairments). Adults are therefore not representative to unravel the development of neuronal correlates of language, cognitive comorbidity and refratoriness in Rolandic epilepsy, ESES, ESES-like or LKS. The study of possible neuronal correlates of language and cognitive impairment and refractoriness in Rolandic epilepsy, ESES, ESES-like and LKS requires the inclusion of an age-matched control group. There are three reasons for doing so. Firstly, all effects will be relative effects and not absolute effects that require a comparison with normal development to be able to understand. Secondly, apart from the secondary changes due to the seizures, brain development in children with Rolandic epilepsy, ESES, ESES-like and LKS may as well differ from healthy subjects. Thirdly, MRI derived cerebral properties such as oxygenation changes due to brain activation and diffusion properties of white matter depends on age, and changes most strongly in the age category that makes up our study population. The imaging of the normally developing brain provides a necessary baseline for comparisons with Rolandic epilepsy, ESES, ESES-like and LKS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

• Diagnosis of Rolandisch epilepsy, ESES, ESES-like or Landau-Kleffner syndrome
• Age of 8 to 18 years
• Clinical and electroencephalographic evidence of seizures.
• Non-symptomatic epilepsy;Healthy control group
Inclusion criteria for healthy control children:
• Children aged 8 to 16 years
• Normal intelligence/following regular schools

Exclusion criteria

• MRI lesions on previous structural brain MRI- or CT-scans or symptomatic epilepsy (e.g. tumours, vascular abnormalities, congenital dysgenesia)
• Progressive neurological disorders
• Other diseases/ causes that may underlie cognitive impairment (i.e. psychiatric diseases)
• Vision less than +4.5D or - 4.5D
• Claustrophobia
• Metal implants or other contraindication for MRI
• Parents not willing to provide informed consent;Healthy control children
Exclusion criteria for the healthy control children:
• Medical history of head trauma or other diseases/ causes that may underlie cognitive impairment (i.e. psychiatric diseases)
• Inability to speak/understand the Dutch language
• Vision less than +4.5D or - 4.5D
• Claustrophobia
• Metal implants or other contraindication for MRI
• Parents not willing to provide informed consent
• Parents who do not want to get informed whenever structural abnormalities are found during imaging

Study design

Design

Study type:	Observational 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):	29-10-2010
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-03-2011
Application type:	Amendment
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	NL32081.068.10
Other	trialregister.nl