Assessment of change in seizure semiology with age and its relation to the development of functional networks in children with partial epilepsy

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

Summary

ID

NL-OMON35223

Source
ToetsingOnline

Brief title
Change in seizure semiology with age

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, fits, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Nationaal Epilepsie Fonds

Intervention

Keyword: age, epilepsy, networks, semiology

Outcome measures

Primary outcome

Evaluate the cause of change in seizures semiology

Analyses will be performed of associations between changes in seizure semiology

and changes in the development of neuronal networks and:

1 changes in underlying brain pathology

2 remote damage (e.g. dual pathology/ mesial temporal sclerosis)

3 the pattern of epileptiform activity during seizure onset, or speed of

seizure spreading

Assessment of differences in neuronal networks in children with and without

epilepsy

1 What are the baseline differences in neuronal networks in children with new

onset partial epilepsy and children without seizures.

2 What are the differences in neuronal networks in children with partial

epilepsy compared to the group of children without seizures three years after

the diagnosis of epilepsy or first assessment in the control group.

Secondary outcome

How often do we see a change in seizure semiology in children

1 How does seizure semiology change? (a definition of change in semiology is

described in the work plan).

2 What are the clinical characteristics of the children in whom seizure

semiology changes? (Characteristics that are examined are described in the work

plan)

3 What is the time course of changing semiology?

Study description

Background summary

Epilepsy is not a rare disorder in childhood. Recurrent seizures may have an impact on cognitive and psychosocial development of the child.
It has been established that seizure semiology in young children with partial epilepsy differs from semiology in adolecents and adults with partial epilepsy. During brain maturation a change of localization of onset and spreading of epileptiform activity may occur. Further, underlying structural brain anormalities may change or new, remote structural damage emerges. How semiology changes in the individual patient with age and its relation to developing functional networks and changes in brain structure has not been investigated until now.

Study objective

The main objective of the study is to achieve knowlegde on change in seizure semiology with age in children with partial epilepsy and to improve the understanding in the cause and consequence of this change, in relation to changing functional networks. A better understanding of this relationship may lead to an earlier prediction of medical intractability. In that case other treatment options can be considered earlier and ideally further damage can be prevented. The ultimate goal is not only to treat the epilepsy, but also to guarantee optimal neuronal development.

Study design

Observational prospective follow-up study of children with partial epilepsy. In retrospect, we will include patients who fullfill the inclusive criteria and visit our specialized outpatient clinic from the first of July 2009 untill we receive permission to start our study.

During a follow up period of 5 years clinical data and data from ancillary investigations will be documented in detail. the following infromation will be obtained from routine patient care: seizure semiology, repetitive EEGs will be performed to assess possible changes in functional networks. Ictal EEG will be performed in patients who experience more than one seizure a week at presentation and in patients who develop a medical intractable epilepsy. To assess changes in or the development of new structural brain abnormalities the brain MRI (including two scientific MRI sequences - which will not influence total MRI time -) will be repeated in all patients with medical resistent epilepsy and in all patients with an initial abnormal brain MRI.

No ancillary investigation is planned for the purpose of this study.

Relationships between age, semiology, functional networks and changes in underlying structural abnormalities will be analyzed.

In children with paroxysmal events without epileptic origin we will conduct MRI scans when it has an added clinical value (good clinical practice). Furthermore, these children will undergo a second EEG 3 to 5 years at the outpatient department to compare characteristics of neural networks with children with partial epilepsy.

Study burden and risks

Part of general patient care, minimal burden, no risks

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3508 AB
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3508 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

1. A total of 30 to 50 children, younger than 17 years of age, with new onset partial epilepsy - who may present with generalized seizures.
2. A total of 30 to 50 children, younger than 17 years of age who were judged, after taking the clinical history and recording of a standard EEG, not to have had seizures (also excluding children with febrile convulsions)

Exclusion criteria

Patients > 16 years of age.
Children with idiopathic generalized epilepsy.

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):	24-09-2010
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-04-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-10-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL27747.041.09