Validity of future risk prediction of electroencephalography (EEG) in complex febrile seizures.

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Primary objective of this study is to investigate whether EEG can be used to predict future febrile or afebrile convulsions. Secondary objectives of this study are to investigate the influence of EEG on antiepileptic drug prescription (will...

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

Summary

ID

NL-OMON41841

Source
ToetsingOnline

Brief title
EEG in complex febrile seizures.

Condition

- Seizures (incl subtypes)

Synonym
febrile convulsion, febrile seizure

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: development, electroencephalography (EEG), febrile seizures, quality of life

Outcome measures

Primary outcome

- Electroencephalography (EEG) results

- Future febrile or afebrile seizures

- Nature of seizures (febrile or afebrile), focal or generalized

- Time to future (a)febrile seizure

Secondary outcome

- Quality of life questionnaire: Infant Toddler Quality of Life QuestionnaireTM

(ITQOL) 10

- Impact of event scale 11

- Development: WPPSI and Bayley-III-NL scores

- Use of anti-epileptic drugs and side effects

Study description

Background summary

Febrile seizures are seizures provoked by fever. This in contrary to epilepsy, which involves unprovoked seizures. Febrile seizures affect 2-4% of children in Europe, and are the most common form of seizures encountered in children. The International League Against Epilepsy defines a febrile seizure as *a seizure in association with a febrile illness in the absences of a central nervous system (CNS) infection or acute electrolyte imbalances in children older than 1 month of age without prior afebrile seizures*. The temperature associated with the febrile illness must be greater than 38.4 degrees Celsius, within 24 hours before or after the seizure. Febrile seizures are most common between 6 months and 5 years.

Febrile seizures can be classified as simple or complex. Simple febrile seizures have no focal features, are short in duration, at least less than 15 minutes, and occur once per 24 hours in a neurologically and developmentally normal child. Complex febrile seizures are seizures that either suggest a focal nature, have a duration of more than 15 minutes, or occur more than once in a period of 24 hours. After experiencing a febrile seizures, the risk of recurrence is elevated compared to the risk in children with no history of febrile seizures (i.e. 30%). After a simple febrile seizure, the risk of developing unprovoked seizures (epilepsy) is not elevated, and development is not interfered. For this reason, these seizures are named benign. Children with complex febrile seizures have a greater risk for development of epilepsy (4-12%)6 and delayed neurocognitive development.

A child with a simple febrile seizure usually does not need to be hospitalized and most children with simple febrile seizures will not be seen by a pediatrician or child neurologist. Despite its excellent prognosis, and its lacking need of future diagnostic evaluations, it is a cause of high anxiety among parents. In a study of Kolahi and Tahmooreszadeh in 20088, it was found that parental fear of febrile convulsions has serious negative consequences affecting daily familial life. It is not sure but plausible that counseling will improve quality of life of parents after the first convulsion. However, it is uncertain whether this group receives adequate counseling.

Most children with complex febrile seizures will be transferred to a hospital to evaluate cause, to exclude a CNS infection and to manage follow up. It is common to recommend an electroencephalography (EEG) for children with complex febrile seizures, to identify the nature of the underlying acute or remote cerebral pathology and to predict the risk of future seizures. However, limited evidence is available to guide future diagnostic evaluations. In a recent Cochrane review by Shah et al. in 2014, it was found that no evidence exists to

support or refute the use of an electroencephalography after complex febrile seizures among children. Whether or not a child with a complex seizure will undergo an EEG, cerebral imaging or future follow up of development is a doctor*s personal choice and might be based on personal experiences.

We plan to do a trial to investigate the rationale of EEG in children with complex febrile seizures. Because the results of EEG are sometimes used to guide antiepileptic drug prescription (which is a potential confounding factor), we aim to do a double blind controlled trial. Two groups are compared. One group with the results of the EEG blinded and one group of children with the results of the EEG open. By comparing these two groups, we can answer the question: does performing an EEG lead to more treatment, but furthermore we can answer the question of the rationale of EEG two years after follow up, when we will open the results of EEG.
Furthermore, we will assess the impact of complex febrile seizures on the quality of life and on neurocognitive and motor development.

Study objective

Primary objective of this study is to investigate whether EEG can be used to predict future febrile or afebrile convulsions.

Secondary objectives of this study are to investigate the influence of EEG on antiepileptic drug prescription (will performing an EEG lead to more anti-epileptic drug prescription). Furthermore whether complex febrile seizures have impact on daily familial life using Infant Toddler Quality of Life QuestionnaireTM (ITQOL) 10 and the impact on neuropsychological and motor development using WPPSI and Bayley-III-NL scores. Finally we will investigate the influence of antiepileptic drug on quality of life, neurocognitive and motor development.

Study design

All patients with a first complex febrile seizure admitted to the hospital or visiting the outpatients clinics (Atrium-Orbis locations Sittard and Heerlen) will be asked to participate in this study. Patients and parents will be given a period of 48 hours to decide whether or not they want to participate. The inclusion period will be 2 years. The follow up period will be 2 years.

All patients will be seen by one of the doctors of the project team. A detailed history will be taken from parents, including perinatal details, family history details, medication, neuropsychological development. A complete neurological and general internal examination will be performed and patients* height, weight and head circumference and blood pressure will be measured.

In general, patients with a complex febrile convulsion will be admitted to the

hospital in order to monitor the patient for one or a couple of days, depending the condition and/or fear of parents. Parents of all patients will be asked to fulfill a questionnaire regarding the impact of the seizure. This will be performed within 48 hours of the seizure.

Because the results of EEG are sometimes used to guide antiepileptic drug prescription (which will influence the future risk of febrile and afebrile convulsions, and is thus a potential confounding factor), we aim to do a double blind controlled trial: patients will be randomly assigned to either the group with the results of the EEG blinded for the doctor and the patients or the group of children with the results of the EEG open (so the doctor and the patient will be informed about the results).

By comparing these two groups, we can answer the question: does performing an EEG lead to more prescriptions of anti-epileptic drugs (which will influence our outcome parameters namely future febrile and afebrile convulsions), but furthermore we can answer the question of the rationale of EEG two years after follow up, when the results of the EEG*s will be revealed and all EEG*s will be used for analysis.

Patients of both groups will undergo an early EEG (within the first week after the seizure) and a late EEG (3 months after the seizure).

After 1, 6, 12 and 24 months children will be seen at the outpatients clinic. Health-related quality of life and its impact on everyday functioning and well-being will be evaluated using ITQOL assessed after 6,12 and 24 months. Furthermore, neuropsychological, motor, and language development will be assessed in the first month of presentation and after 2 years by using the Bayley Scales of Infant Development-third Edition-Dutch edition (Bayley-III-NL) for children between 6-30 months at presentation and the WPPSI (Wechsler Preschool and primary scale of intelligence) for children between 30 months till 7 years.

Study burden and risks

The only intervention is EEG. It is not sure whether or not EEG now routinely performed in children with complex febrile convulsions is of any benefit. If it might not predict future epilepsy, it might not be routinely performed. This is beneficial from point of view of the health costs and the patients burden, and furthermore may lead to less prescriptions of anti-epileptic drugs (with less medication related side effects).
*

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

First febrile complex seizure
Age between 6 months and 5 years
Children with a normal mental and motor development

Exclusion criteria

Diagnosis of epilepsy, febrile or afebrile seizures in history.
Diagnosed with an underlying neurological disease (like mental retardation, cerebral palsy, behavioral disorders)
Mental or motor impairment
Diagnosed with an intracerebral infection (e.g. meningitis, encephalitis)
Recent trauma capitis

Use of antiepileptic drugs
Born prematurely (before 32 weeks of gestation)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	07-04-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	26-08-2019
Application type:	Amendment

Review commission: METC Atrium-Orbis-Zuyd

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	NL50982.096.14