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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20967

Source
NTR

Brief title
EEG in complex febrile seizures

Health condition

febrile seizures, EEG, quality of life, development
koortsconvulsies, EEG, kwaliteit van leven, ontwikkeling

Sponsors and support

Primary sponsor: Zuyderland Medical Center
Source(s) of monetary or material Support: B.Panis Zuyderland Medical Center

Intervention

Outcome measures

Primary outcome

EEG results

Number of future febrile or afebrile seizures

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

Time to future febrile or afebrile seizure

Secondary outcome

Quality of life questionnaire: Infant Toddler Quality of Life QuestionnaireTM (ITQOL)

Impact of event scale

Development: WPPSI and Bayley-III-NL scores

Use of AEDs 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.

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%) 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.

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 EEG 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 AED 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

this study hypotheses that EEG does not predict future seizures. If correct abandoning routinely EEG will lead to a reduction in health costs and patient/family burden. Furthermore, neurocognitive development will be investigated two years after the first febrile seizure and impact of life will be assessed.

Study design

Two years of inclusion, 2 years of follow up

Intervention

EEG

Infant Toddler Quality of Life QuestionnaireTM (ITQOL)

Impact of event scale

WPPSI and Bayley-III-NL neuropsychological tests

Contacts

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Eligibility criteria

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 AED

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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-01-2016
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-01-2016
Application type:	First submission

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
NTR-new	NL4464
NTR-old	NTR5706
Other	14T131 : METC Z

Study results