

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

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this study hypothesises 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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20967

Bron

NTR

Verkorte titel

EEG in complex febrile seizures

Aandoening

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

Ondersteuning

Primaire sponsor: Zuyderland Medical Center

Overige ondersteuning: B.Panis Zuyderland Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Febrile seizures are seizures provoked by fever. This is 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 seizure, 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.

Doel van het onderzoek

this study hypothesises 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.

Onderzoeksopzet

Two years of inclusion, 2 years of follow up

Onderzoeksproduct en/of interventie

EEG

Infant Toddler Quality of Life QuestionnaireTM (ITQOL)

Impact of event scale

WPPSI and Bayley-III-NL neuropsychological tests

Contactpersonen

Publiek

Zuyderlands Ziekenhuis Heerlen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

First febrile complex seizure

Age between 6 months and 5 years

Children with a normal mental and motor development

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	25-01-2016
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	30-01-2016
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	NL4464
NTR-old	NTR5706
Ander register	14T131 : METC Z

Resultaten