

Stress and childhood 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-OMON39835

Source

ToetsingOnline

Brief title

Stress and childhood epilepsy

Condition

- Seizures (incl subtypes)

Synonym

Epilepsy, seizure disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W, Stichting Bio Kinderrevalidatie

Intervention

Keyword: children, epilepsy, stress

Outcome measures

Primary outcome

The main study outcome is the difference in maximum level of cortisol during the Trier Social Stress Test between children with stress sensitive seizures, children with non stress sensitive seizures and healthy controls.

Secondary outcome

The secondary study parameters are the differences in:

- diurnal cortisol variability;
- hippocampal function; and
- genetic polymorphisms

between children with stress sensitive seizures, children with non stress sensitive seizures and healthy controls.

Study description

Background summary

Epilepsy is very common in childhood. Seven out of every 1000 children is diagnosed with epilepsy. Stress is one of the most frequently self-reported provocations of seizures in children with epilepsy. Animal studies showed that in animals with epilepsy, stress hormones influence the susceptibility to seizures. The underlying mechanism of stress-sensitivity of seizures in childhood epilepsy is unknown.

We hypothesise that in children with stress-sensitive seizures, stress hormone regulation is altered compared to children whose seizures are not sensitive to stress and healthy controls; and that stress sensitivity of seizures is related to hippocampal function as well as genetic background. More knowledge of the relation between stress and childhood epilepsy will lead to better counselling

of children with epilepsy and their parents on how to deal with stressful situations, and may provide directions for the development of new treatment strategies.

Study objective

The overall aim of this project is to elucidate the interaction between stress and epileptic seizures in childhood epilepsy. The specific aim of this study is to compare the possible differences in stress hormone regulation, hippocampal function and genetic background between children with stress sensitive seizures, children without stress sensitive seizures and healthy controls.

Study design

Prospective observational explorative study without invasive measurements

Study burden and risks

The burden for participating children consists of completing a six-week diary, two questionnaires for children 11-17 years of age, one testing day and 4 saliva samples at home. For parents, the burden consists of helping the child with the diary and saliva samples, accompanying the child at the testing day (one parent), and four to six questionnaires for both parents.

The burden of keeping this diary is expected to be minor, as most parents of children with epilepsy already keep a diary of seizures. The testing day will take approximately 3 hours and 15 minutes, in which study participants undergo the Trier Social Stress Test for Children (TSST-C). During this test, heart rate and blood pressure will be monitored. This is non invasive, but blood pressure measurement can cause an unpleasant tight feeling around the upper arm. At nine time points, saliva samples will be obtained by chewing on a cotton swab. This is non invasive, but the child may find the taste objectionable. The code of conduct related to expressions of objection by minors participating in medical research, as stated by the CCMO, will be followed. Participants are asked to perform two tasks, comparable to a school examination. The evoked moderate psychosocial stress response is of comparable intensity to stressful situations experienced in daily life, with the advantage that the stress response can be measured in a controlled setting (this test was previously used in study 08/271, *Long-term effects of neonatal glucocorticoid treatment on health in later life (follow-up study)*). For this reason, the risk of provoking seizures, even in patients with stress sensitive seizures, is not expected to be increased compared to the everyday situation. As two-thirds of the study population consists of children with active epilepsy, it is possible that the test will coincide with a seizure. Although these seizures could also happen while being at home, extra medical safety is expected because the experiments take place in a study environment. For this reason, children of whom parents report a prolonged or life threatening seizure in response to

acute stress are excluded. During the TSST-C a parent/caregiver of the child will be waiting nearby, so that anti-epileptic medication can be administered by the parent if necessary. Also, a general physician will be present during the total duration of the TSST-C.

The four saliva samples at home will be taken by children themselves or with assistance from their parents, with the same cotton swabs used during the TSST-C. This will take 45 seconds at three mornings just after awakening and at one evening. For this procedure, the same considerations apply as mentioned above. The parental questionnaires take 10 minutes per parent to complete, the questionnaire about life events also takes 10 minutes to complete.

We believe that using these precautionary measures, the risks of this study are negligible. Because this study will include children below 12 year of age, the risks will be upgraded to *minimally exceeding the negligible risk*.

The study population consists of children instead of adults because the research main question about the difference in stress response between children with and without stress sensitive seizures can not be answered studying an adult population. Hormonal stress response is age dependent and characteristics of paediatric epilepsy differ from epilepsy in adults. Overall, children with epilepsy have a high seizure frequency compared to adults. Also, children are more sensitive to seizure precipitating factors. We therefore expect results in adults to differ from results in children.

By participating in this study, children and their parents will contribute to improvement of the current knowledge of the pathogenesis of stress sensitive seizures. We aim to improve counselling children with epilepsy as well as their parents and school teachers on how to deal with stressful situations, and desirably will also provide a foundation for the development of new treatment strategies for children with stress sensitive seizures.

Contacts

Public

Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584 EA
NL

Scientific

Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584 EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Children with epilepsy:

- Patients between 6 to 17 years of age
- Established diagnosis of epilepsy
- Mean seizure frequency of at least 1 seizure a year

Healthy controls:

- Age and gender matched to a child with epilepsy that is included in the study, not diagnosed with any chronic disease

Exclusion criteria

o In patients with epilepsy:

- Any doubt about the diagnosis epilepsy
- No distinction possible between (co-existing) seizures of (possible) non-epileptic origin and epileptic seizures by parents and/or treating paediatric neurologist
- Seizure free since brain surgery or brain surgery scheduled in the following months
- Reported status epilepticus in response to acute stress;in total study population:
- Children with assessed or expected (based on school level) intelligence quotient (IQ) or IQ estimate (calculated from developmental age) <70
- Children with chronic co morbidities (e.g. psychiatric disorder)
- Use of medication known to influence HPA-axis functioning (e.g. oral contraceptives, corticosteroid medication, ACTH receptor agonists)
- Heavy smoking (> 10 cigarettes a day)
- Heavy alcohol consumption (> 60g a day)

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):	22-11-2012
Enrollment:	123
Type:	Actual

Ethics review

Approved WMO	
Date:	09-10-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	09-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	05-02-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	08-10-2014
Application type:	Amendment

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	NL40158.041.12