

Children*s Autoimmunity related to Neuropsychiatric symptoms, Chorea and Epilepsy

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(1) To determine the frequency of antibody-mediated encephalopathy in children with seizure-related or (sub)acute onset neuropsychiatric disorders. (2) To identify the target auto-antigens of selected seizure-related and (sub)acute onset...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON41693

Source

ToetsingOnline

Brief title

CHANCE

Condition

- Autoimmune disorders
- Central nervous system infections and inflammations
- Psychiatric and behavioural symptoms NEC

Synonym

'autoimmune encephalitis' and 'inflamed brain'

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,NWO Veni-incentive

Intervention

Keyword: antibodies, children, encephalitis, neuropsychiatric

Outcome measures

Primary outcome

1. The characterization of new antibody-related clinical syndromes; 2. The frequency of the individual antibody-mediated syndromes in children; 3. The outcome of the individual antibody-mediated syndromes in children.

Secondary outcome

not applicable

Study description

Background summary

The CHANCE study aims to establish antibody associations and the autoimmune origin of several epileptic and neuropsychiatric disorders of unknown etiology in children, and investigate the effects of the antibodies on cell surface and neurotransmitter synaptic receptors. Recently an expanding group of antibody-mediated autoimmune encephalitis was discovered which associated with seizures, status epilepticus or behavioral symptoms occurring alone or with other symptoms. The impact of these studies has been immediate: seizure disorders previously considered *fever-induced*, idiopathic or *possibly viral* are defined as autoimmune and treatable, as patients recover with immunotherapy. This work has led us to hypothesize that many acquired seizure/neuropsychiatric disorders of unknown etiology including new-onset seizures/status epilepticus related to encephalitis, fever-induced refractory epileptic encephalopathy in school-age children (FIRES) and pediatric autoimmune neuropsychiatric disorders associated with streptococcus (PANDAS) are mediated by antibodies affecting neurotransmitter receptors at cell surface or synaptic sites.

Study objective

(1) To determine the frequency of antibody-mediated encephalopathy in children

with seizure-related or (sub)acute onset neuropsychiatric disorders.

(2) To identify the target auto-antigens of selected seizure-related and (sub)acute onset neuropsychiatric disorders in children for which we have preliminary evidence of antibodies to neuronal cell surface/synaptic proteins, and

(3) To assess the effects of the antibodies on neurons and/or synapses in vitro and, for the most interesting 1 or 2 antibodies/antigens, in vivo.

Study design

Observational cohort study

Study burden and risks

The study patients will have one venapuncture, with negligible risks and burden. The diseases at hand are mainly age-group specific, and as the brain and immune system are different in adults from children the study cannot be extrapolated from studying adults.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Age under 18 years
- Clinical profile fits one of the four groups: 1. limbic or cortical encephalitis, 2. new-onset seizures/status epilepticus without known cause, 3. acute encephalopathy with fever/inflammation-mediated status epilepticus or 4. acute-onset neuropsychiatric symptoms of basal ganglia dysfunction, like chorea .
- No known cause, like a bacteria, virus, haemorrhage, stroke, genetic cause.

Exclusion criteria

- 18 years or over
- Patient and/ or legal representative is withholding informed consent
- Patient objects after initial informed consent (see paragraph 8.3).

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 28-01-2015

Enrollment: 600

Type: Actual

Ethics review

Approved WMO

Date: 20-06-2014

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 20-03-2015

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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

CCMO

ID

NL47872.078.14