Antibodies Causing Epilepsy Syndromes

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(1) To determine frequency of antibody-mediated encephalopathy in adults with new-onset epilepsy/status epilepticus or chronic epilepsy. (2) To assess outcome of antibody-mediated encephalopathy in adults with epilepsy, and identify markers for good...

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

Summary

ID

NL-OMON44684

Source
ToetsingOnline

Brief title
ACES Study

Condition

- Autoimmune disorders
- Central nervous system infections and inflammations

Synonym
auto immune encephalitis, 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),Nationaal Epilepsie Fonds

Intervention

Keyword: Antibodies, Autoimmunity, Encephalitis, Epilepsy

Outcome measures

Primary outcome

1. characterise new antibody mediated clinical syndromes causing epilepsy.

2. Measure the frequency of every individual antibody mediated syndrome causing epilepsy in adults.

3. Look at outcome of individual antibody mediated syndrome causing epilepsy in adults.

Secondary outcome

- What clinical and epidemiological markers are linked to the specific, individual antibodies?

- What markers define poor or good prognosis in adults?

Study description

Background summary

Recently new treatable causes of epilepsy have been identified. These disorders are caused by a disruption of the balance in the brain caused by inflammation.This inflammative reaction is caused by an autogene reaction of the immune system to specific brain proteins. The body produces antibodies to specific parts of the brain. These disorders can lead to epilepsy, memory and psychiatric problems. Recognition is necessary for good treatment. Mostly anti-epileptic drugs are not sufficient. The disease can be treated with immmunemodulating therapy. The ACES Study will focus on finding new, not ready known antibodies, causing epilesy. Therefore we will regard patients with epilepsy of unknown origin. To find new antibodies we need to add sera of patients with epilepsy to cultivated cells to look for a reaction. If we detect new antibodies we will map clinical features of the patientes. Also we will determine the effects of antibodies on brain cells. Finding of new antibodies can provide new treatment options for these patients. Also this will able us to

find out more about the etiology of epilepsy.

Study objective

(1) To determine frequency of antibody-mediated encephalopathy in adults with new-onset epilepsy/status epilepticus or chronic epilepsy.
(2) To assess outcome of antibody-mediated encephalopathy in adults with epilepsy, and identify markers for good or poor prognosis.
(3) To identify the target auto-antigens of selected epilepsy syndromes in adults for which we have preliminary evidence of antibodies to neuronal cell surface/synaptic proteins.
(4) 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

Prospective Observational Cohort Study.

Study burden and risks

The study patients will have one venapunction, with negligible risks and burden. Patients from cohort 1 (status epilepticus and new onset epilepsy wuth suspicion of encephalitis) frequently have a decreased consiousness, as manifestation of the disease. The study is only applicable in clinically affected patients and can thus only be carried out in this group of incompetent patients. For patients in cohort 2 (chronic epilepsy patients) this will not be an issue.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age of 18 and older.
- Status epilepticus or new onset seizures with signs of limbic encephalitis (clinical picture, MRI (FLAIR abnormalities), EEG abnormalities or CSF findings (CSF pleocytosis, increased IgG index, oligoclonal bands)
- Patients with acquired chronic focal epilepsy with an unknown cause.
- A subgroup of these patients, with chronic focal epilepsy, undergoing epilepsy surgery (without a known underlying cause of their epilepsy or possible (post) encephalitis changes, like mesiotemporal sclerosis and hippocampal sclerosis). These are patients with a pharmacoresistent epilepsy, not responding to first and second-line anti-epileptic drugs.

Exclusion criteria

Patients < 18 years.
Epilepsy with known cause.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2014
Enrollment:	1380
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-01-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-07-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2017

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	ID
ClinicalTrials.gov	NCT02802475
CCMO	NL50096.078.14