The Genetics of epilepsy

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Primary objective: To set up a repository of genetic material from a large group of well phenotyped people with epilepsy patients to allow the case control association studies, to analyze and detect genetic risk factors for epilepsy. Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON35608

Source
ToetsingOnline

Brief title
Genetics of epilepsy

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Epilepsy, Genetics

Outcome measures

Primary outcome

Genetic variation in genes that potentially predispose to epilepsy, yet have

limited predictive value at an invidual level.

Secondary outcome

None

Study description

Background summary

The epilepsies are likely to be due to a combination of genetic and environmental factors or are triggered by an interaction of such factors in susceptible individuals. Some of the genetic risk factors have been identified by examining families with (rare) hereditary epilepsies. Epileptic disorders have been associated to mutations in genes that code ion channels, or neuronal receptors, but also in genes that have no direct relation to neuronal electrophysiology. The study of epilepsy genes may contribute to a better understanding of the molecular mechanisms, and lead to the development of better therapies for the condition.

Study objective

Primary objective: To set up a repository of genetic material from a large group of well phenotyped people with epilepsy patients to allow the case control association studies, to analyze and detect genetic risk factors for epilepsy.

Secondary objective: To examine in this cohort genetic factors that determine refractoriness to anti-epileptic medication and common side-effects of anti-epileptic medication.

Study design

Collection of cases for a case control study.

Study burden and risks

The burden of participation will be a single venapuncture for 20 ml of blood and supplying some additional information. The benefit will be that more knowledge of the disease will be achieved when important genetic risk factors are identified. The secondary objectives will contribute to the improvement of the treatments for epilepsy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Any patient regardless of age or gender willing and able to provide informed consent ;- Children and persons unable to consent may be included if their parents or legal representative provide informed assent ;- A firm diagnosis of epilepsy based either on

history, clinical examination or EEG regardless of type with a history of at least two independent epileptic seizures. ;- Etiological diagnosis supported by imaging, whenever appropriate

Exclusion criteria

- Patient unwilling to provide consent or if parents or legal representative are unwilling to assent. ;- Diagnosis of epilepsy not corroborated by ancillary investigations ;- Age under 12 years

Study design

Design

Study type:	Observational 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):	22-07-2010
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2010
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	24-04-2013
Application type:	Amendment
Review commission:	METC NedMec

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	NL29090.041.09