Peripheral nerve excitability in paroxysmal brain disorders

Published: 02-07-2014
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To investigate whether the peripheral nervous system is involved in paroxysmal neurological conditions.

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

Summary

ID

NL-OMON40646

Source
ToetsingOnline

Brief title
excitability in paroxysmal brain disorders

Condition

- Neurological disorders congenital

Synonym
paroxysmal neurological disorders

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: Christelijke Vereniging voor de Verpleging van Lijders aan Epilepsie

Intervention

Keyword: Excitability, Paroxysmal neurologic disorders, Peripheral nervous system

Outcome measures

Primary outcome

EMG measures

Secondary outcome

Concentration of Na, K, Mg, Ca in blood

Study description

Background summary

Some paroxysmal neurological conditions are caused by alterations of ionchannels of the peripheral and central nervous system.
So far, little is known about the effects that such conditions have on the peripheral nervous system. With surface EMG (electromyography), it can be investigated whether the peripheral nervous system is also altered in paroxysmal neurological conditions.

Study objective

To investigate whether the peripheral nervous system is involved in paroxysmal neurological conditions.

Study design

Cross-sectional case-control study

Study burden and risks

EMG is a non-invasive technique that can lead to mild discomfort in some cases. Blood withdrawal via venipuncture in the elbow has a very low rate of adverse events. The needle puncture may cause bruising and in very rare cases an infection of the skin or blood vessel may occur at the puncture site.

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

good general health
18 y or older
normal cognitive functioning
speaking dutch

Exclusion criteria

use of medication with known effect on ion channel function
history of neuropathy or motor neuron disease
diabetes mellitus
pregnancy

any neurological disorder (healthy controls)
psychiatric disorder requiring treatment by psychiatrist
1st degree family member with epilepsy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	02-07-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL48452.058.14