Increasing diagnostic accuracy in patients with myoclonic disorders. Giant potential measurements with multichannel SSEP

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Objectives: To optimize SSEP recording methods to improve diagnostic procedures in myoclonic disorders. More precisely, to determine whether enhanced N35 potentials are more commonly found using multichannel (64 channels) SSEP versus conventional (5...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON32617

Source
ToetsingOnline

Brief title
Multichannel SSEP in myoclonic disorders.

Condition

- Movement disorders (incl parkinsonism)

Synonym
myoclonus, shaking, trembling

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diagnosis, giant potential, multichannel SSEP, myoclonus

Outcome measures

Primary outcome

Main study parameters/endpoints:

Part A: localization and amplitude of N35 potentials using multichannel SSEP

compared to results of standard SSEP in individuals with a cortical myoclonic

disorder and in healthy subjects. Part B: identical to part A for subcortical

myoclonus and dystonia.

Secondary outcome

nvt

Study description

Background summary

Rationale: Currently, clinical history and physical examination are the basis to discriminate between myoclonic disorders. However, clinical criteria are usually not sufficient. To differentiate between myoclonic disorders, somatosensory evoked potential (SSEP) measurement can be helpful. In previous studies, a giant potential was found in cortical myoclonus, and a less enlarged potential in subcortical myoclonus and dystonia, as compared to healthy controls. Large intersubject variability however reduces the predictive value. Multichannel SSEP will probablymay reduce intersubject variability and shorten diagnostic procedures in these patients.

Study objective

Objectives: To optimize SSEP recording methods to improve diagnostic procedures in myoclonic disorders. More precisely, to determine whether enhanced N35 potentials are more commonly found using multichannel (64 channels) SSEP versus conventional (5 channels) SSEP in patients with cortical myoclonus.

Furthermore, to determine which electrodes represent the largest amplitude of the enhanced N35 potential in patients compared to healthy controls. Also, to observe possible differences in the influence of medication on amplitude and latency of N35-measurement. And finally, to investigate differences in amplitude and localization of potentials between patients diagnosed with cortical myoclonus, subcortical myoclonus and dystonia.

Study design

Study design: Case-control study

Study burden and risks

Patients will undergo one site visit, during which standardized clinical evaluations will be performed with the aid of clinical scales and videos. They will be checked for other neurological conditions. During the same visit, patient will undergo a SEPP measurement recording. Healthy subjects will undergo the same procedure.
The proposed investigation bears virtually no risks and is usually well tolerated. Eventually, the aim of this study is to improve and shorten the diagnostic process of myoclonic disorder. Healthy controls will have no special benefits.

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

Group A: patients with strong clinical suspicion of cortical myoclonus
Group B: patients with strong clinical suspicion of dystonia
Group C: patients with strong clinical suspicion of subcortical myoclonus
Group D: matched healthy controls

Exclusion criteria

Other neurological disorders than the above mentioned.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2010

Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL29978.018.09