Quantification of motor and sensory aspects of tonic dystonia

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

Summary

ID

NL-OMON38007

Source
ToetsingOnline

Brief title
Motor and sensory aspects of tonic dystonia

Condition

- Movement disorders (incl parkinsonism)

Synonym
fixed dystonia, muscle cramps, muscle spasms

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Ministerie van Economische Zaken

Intervention

Keyword: dystonia, measurement, quantification, tonic

Outcome measures

Primary outcome

1) Accuracy of joint position sense and motion

2) Selectivity of muscle activation.

3) Recognition of hand laterality.

4) Sensory function including two-point-discrimination, vibration sense, pain

threshold of muscles.

Secondary outcome

None.

Study description

Background summary

Background: Dystonia is a poorly understood disorder characterized by a decrease or loss of voluntary muscle control associated with decreased inhibition, changes in sensory processing and problems in sensorimotor integration. Uncovering the interrelations among these aspects will likely contribute to a better understanding of the condition. Dystonia is the most frequently encountered movement disorder after peripheral trauma and frequently occurs in the context of Complex Regional Pain Syndrome.
The study is expected to yield valuable information regarding differences in sensory and motor processing between patients and controls. Additionally, knowledge on the influence of sensory function on motor performance may not only lead to a better insight in the sensorimotor integration in dystonia, but may provide clues on how to use motor paradigms, sensory stimuli and sensory manipulation to improve motor performance in patients with tonic dystonia. The results are expected to raise new research questions which may instigate follow-up research.

Study objective

The objective of the present study is to obtain a better understanding of tonic dystonia by quantification of the motor and sensory characteristics of the condition, and to assess the relationship between both these parameters. Specifically, this study aims to further our understanding of the voluntary-automatic dissociation phenomena and the processes underlying coherence entrainment in these patients. To this end, both intentional and unintentional sensorimotor integration is examined.

Study design

Cross-sectional case-control design.

Study burden and risks

The assessment procedure involves the completion of questionnaires (which will take approximately 15 minutes) and the performance of motor tasks (approximately two hours). Some fatigue in patients may be expected. Some temporary discomfort in patients (due to the length of the protocol) cannot be ruled out completely.

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

Male or female patients diagnosed with CRPS with or without tonic dystonia of one or both upper extremities who are 18 years or older, have command of the Dutch language and are registered at the LUMC.

Exclusion criteria

mobile dystonia; known genetic form of dystonia, e.g. DYT1-DYT17, Wilson*s disease; lesions or diseases of the central nervous system (e.g. as a result of head trauma); implantation of drug-delivery pump for intrathecal baclofen or other spasmolytic medication.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2010
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL29310.058.09