Cervical dystonia, confirming the discriminative value of a new diagnostic method

Published: 26-08-2013
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-To confirm the potential of a diagnostic tool to discriminate dystonic from non-dystonic muscles in CD patients-To explore the potential to discriminate CD patients from Functional Torticollis (FT) patients

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

Summary

ID

NL-OMON40531

Source
ToetsingOnline

Brief title
cervical dystonia

Condition

- Movement disorders (incl parkinsonism)

Synonym
cervical dystonia, spasmodic torticollis, wry neck

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: STW financiert het project. Het budget van STW is afkomstig van NWO en van het ministerie van economische zaken,Cruden,Ipsen

Pharmaceuticals,Motek medical bv,TMSi: Test Measurement systems inc.

Intervention

Keyword: botulinum treatment, cervical dystonia, muscle selection, spasmodic torticollis

Outcome measures

Primary outcome

The accuracy of the new method in muscle selection. The accuracy will be

calculated using the diagnostic odds ratio, sensitivity and specificity.

Secondary outcome

The differences in characteristics and distribution of abnormal activation

patterns between CD patients and FT patients .

Additional outcome in CD patients that are currently receiving BTX treatment:

The differences in characteristics and prevalence of abnormal activation

patterns before and after botulinum toxin treatment.

Study description

Background summary

Cervical dystonia (CD), also called spasmodic torticollis, is characterized by sustained involuntary muscle contractions of the neck leading to debilitating abnormal postures, pain and twisting movements. The first line of treatment in CD are intramuscular botulinum toxin (BTX) injections in the dystonic muscles. The diagnosis CD is a based on clinical examination and observation and no definite additional diagnostic tools are available. Accurate diagnostic tools are required for proper selection of dystonic muscles for BTX treatment and for confirmation of the clinical diagnosis.

Study objective

-To confirm the potential of a diagnostic tool to discriminate dystonic from non-dystonic muscles in CD patients

-To explore the potential to discriminate CD patients from Functional Torticollis (FT) patients

Study design

Case-control pilot study.

Methods: A new developed isometric contraction device (see 8.3) will be used to identify dystonic muscles. The identification is based on specific abnormal muscle activation patterns during isometric force tasks in different directions. To confirm the discriminative value for muscle selection in CD patients we will compare the muscles selected by the new method to the clinically identified muscles (*gold standard*) in CD patients. In addition, to explore the potential to discriminate CD patients from FT patients, we will compare (abnormal) activation patterns across these groups.

Study burden and risks

Patients and controls will have to come to the AMC for 2-3 hours. They will undergo a neurological examination, fill out a questionnaire and participate in the experiment. This experiments might lead to minor discomfort but the risks associated with the experiment are minimal.
To investigate/rule out any effects of botulinum toxin treatment on the results, the CD patients that are currently treated with botulinum toxin will be measured twice: once before the botulinum toxin treatment and once 4 weeks after the treatment.

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

Patients with idiopatic cervical dystonia
Age of onset *26
botulinum toxin treatment naive or last treatment more then 3 months ago
Informed consent

Exclusion criteria

Fixed dystonia (often considered a sign of psychogenic torticollis)
Secondary dystonia
Use of neuropharmaceuticals
Pregnancy

Study design

Design

Study type:	Observational 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):	29-11-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	isometric contraction device
Registration:	No

Ethics review

Approved WMO Date:	26-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2014
Application type:	Amendment
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	NL44382.018.13