Driving performance in cervical dystonia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28122

Source
Nationaal Trial Register

Brief title
DriveID study

Health condition

Cervical dystonia
Spasmodic torticollis

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Fonds Nuts Ohra
Jacques & Gloria Gossweiler Foundation
Hogeschool van Amsterdam, lectoraat oefentherapie
Wetenschapsfonds dystonie

Intervention

Outcome measures

Primary outcome

- Driving performance (standard deviation of
lateral position on the road)
- Driving safety (The number of crashes and

other traffic conflicts such as near crashes.
Rule violations like not giving right of way
and driving hindrance which includes
norm violations like travelling under the
speed limit or stopping unreasonably far
away from a stop line or traffic light
- Fitness To Drive Screening measure

Secondary outcome

- Range of motion and kinematics of the head
- Gaze behaviour
- Perceived fatigue and Driving effort

Study description

Background summary

Background: Cervical Dystonia (CD) is characterized by involuntary muscle contraction of the neck and abnormal positions of the head that affects daily life activities and social life of patients. For most people, being able to drive a vehicle is a very important part of their daily life. However, it is likely that driving performance and driving safety are affected due to the involuntary muscle contractions and abnormal postures. Although Botulinum Toxin (BTX) treatment improves motor symptoms and head postures in 70-92% of CD patients, many patients still have difficulties with the execution of voluntary and controlled movements of the neck and head. Up to date, there is no literature available about driving performance and driving safety in CD patients.
Study objectives: To investigate the differences in driving performance and safety between CD patients and healthy controls in a driving simulator. To compare the subjective evaluation of the difficulty of various aspects of the driving task in subjects with CD patients and healthy controls with the Fitness To Drive Screening.
Study design: The study will be performed as an explorative case-control pilot study.
Study population: 10 subjects patients with idiopathic cervical dystonia and 10 healthy age and sex matched controls.
Primary outcomes: Driving performance, driving safety and the Fitness To Drive Screening. Driving performance is measured as the standard deviation of the lateral position in the lane, time to lane crossing, and number of lane crossings. Driving safety is measured by the number of (near) crashes and other traffic conflicts such as near crashes and rule violations.
Measurements: Measurements will be performed eight to ten weeks after BTX injections. All subjects will fill in the Fitness To Drive Screening and perform three driving tests in a driving simulator. The first test consists of a swing drive where patient drive a winding route. The second test consists of a route involving intersections and the third consists of a highway route with a merging task.
Expected results: It is expected that subjects with CD patients perform less well than healthy

controls with respect to driving performance and driving safety. We expect limitations in tasks requiring movements opposite to the personal dystonic posturing of the patients.

Study objective

Driving a motor vehicle is a functional task requiring a complex interaction of visual, cognitive and motor skills. A wide range of acute and chronic medical conditions may impair driving performance and safety. Since CD is characterized by involuntary movements and /or abnormal postures of the neck and head it might affect driving performance and safety.

Study design

measurements will only be performed just after the simulation drives

Intervention

6 drives in a driving simulator

Contacts

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Eligibility criteria

Inclusion criteria

- 30 years or older
- Stable on BTX for at least 1 year
- Able to drive
- Have driven in the last 12 months
- Have given written and informed consent

Exclusion criteria

- Secondary (including psychogenic) dystonia
- Hereditary (dominant) forms of dystonia
- Segmental, hemi-, multifocal or generalized dystonia
- Subjects who underwent neurosurgery
- Inability to understand written and spoken Dutch language
- Motion sickness

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40247
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4301
NTR-old	NTR4446
CCMO	NL45887.042.13
OMON	NL-OMON40247

Study results