Driving performance in patients with idiopathic cervical dystonia; a driving simulator pilot study

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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 driving in CD patients...

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

Summary

ID

NL-OMON40247

Source
ToetsingOnline

Brief title
Driving performance in cervical dystonia
DriveID-study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cervical dystonia, Spasmodic Torticollis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Fonds NUTSOhra;Jacques and Gloria

Gossweiler foundation;Wetenschapsfonds dystonievereniging

Intervention

Keyword: Cervical dystonia, Driving performance, Driving simulator, Spasmodic Torticollis

Outcome measures

Primary outcome

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. Data will be retrieved from the driving simulator

Secondary outcome

Range of motion and movement speed of the head will be measured with a portable device that uses motion sensors that combines a gyroscope, accelero- and magnetometer to capture a complete three-dimensional spectrum of the head movements.

Gaze behaviour by filming the driver*s face while driving. The drivers face will be captured by a HD camera (Sony HDR CX 210E) mounted on top of the simulator in front of the driver. In order to analyze the gaze behavior, video recordings of participants* face are coded and analyzed. The Drivers face is manually labeled with ELAN, a tool used to make complex annotations on videos.

Perceived fatigue of the neck and shoulder aera and driving effort will be

rated just before and just after the simulated drive, using the Borg CR-10 scale. The Borg CR-10 scale is an 11 point rating scale, ranging from 0 to 10 on which monitors perceived fatigue and driving effort during the performance of a driving task.

Study description

Background summary

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 objective

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 driving in CD patients and healthy controls with the Fitness To Drive Screening.

Study design

The study will be performed as an explorative case-control study.

Study burden and risks

Some persons might experience some dizziness or nausea while driving in the simulator. This is mainly caused by the fact that movement is seen but not felt. When a person gets dizzy or nauseous, the simulator will be stopped.

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

- 30 years or older
- Stable on Botulinum Toxin for at least 1 year
- 30 years of age or older
- Having a drivers license
- Have given written informed consent for participation
- Able to drive
- Have driven in the last 12 months

Exclusion criteria

- Secondary (including psychogenic) dystonia

- Hereditary (dominant) forms of dystonia
- Segmental, hemi-, multifocal or generalized dystonia
- Patients who underwent neurosurgery
- Inability to understand written and spoken Dutch language
- Motion sickness
- Medication that is known to influence driving performance

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28122
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45887.042.13
Other	NTR
OMON	NL-OMON28122