Driving performance in cervical dystonia

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28122

Bron
Nationaal Trial Register

Verkorte titel
DriveID study

Aandoening

Cervical dystonia
Spasmodic torticollis

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Fonds Nuts Ohra
Jacques & Gloria Gossweiler Foundation
Hogeschool van Amsterdam, lectoraat oefentherapie
Wetenschapsfonds dystonie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

measurements will only be performed just after the simulation drives

Onderzoeksproduct en/of interventie

6 drives in a driving simulator

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40247
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten