An observational study to evaluate driving competence in Huntington's disease

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Primary objectives:- To investigate possible differences in driving performances between premanifest gene carriers, manifest HD, and control subjects.- To explore if different aspects of cognitive functioning might be a predictor of fitness to drive...

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

Summary

ID

NL-OMON43584

Source
ToetsingOnline

Brief title
Evaluating driving competence in HD (Drive-HD)

Condition

- Movement disorders (incl parkinsonism)

Synonym
Huntington's disease, movement disorder

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: door CHDR;en betrokken onderzoekers van het LUMC worden betaald vanuit andere projecten die gefinancierd zijn door derde

geldstroom

Intervention

Keyword: driving, Huntington's disease

Outcome measures

Primary outcome

Primary end-points:

- difference between the groups in number of errors on the outcome variables of the driving simulator.

- difference between the groups in scores on the neuropsychological and motor assessments.

Outcome measures:

Driving simulator

- Standard Deviation of Lateral Position (SDLP)

- Mean, maximum and standard deviation of vehicle speed

- Velocity, acceleration, position on the road, right of way, distance to preceding car, time to collision

Neuropsychological and behavioural assessments

- SDMT: total number of correct responses in 90 seconds

- Stroop: total number of correct responses per trial

- TMT: completion time in seconds for each trial

- SART: the total number of errors

- Adaptive tracking task: average performance (%)

- PBA-s: total score per domain defined as severity multiplied by frequency

Motor assessments

- UHDRS TMS: total motor score (range 0-124)

- UHDRS TFC: total functional score (range 0-13)

- Finger tapping: mean tapping rate and standard deviation

- Saccadic eye movements: saccadic reaction time (seconds), saccadic peak velocity (degrees/second), saccadic inaccuracy (%)

- Smooth pursuit eye movements: percentage of time the eyes are in smooth pursuit of the target (%)

- Body sway: antero-posterior sway (mm)

Questionnaires and evaluation

- FrsBe: overall total score and total score per subscale

- HADS-SIS: total scores per domain

- Evaluation: grade given by patient and companion

Secondary outcome

Secondary end-points:

- a correlation between behavioural changes, as measured using the PBA-s, and driving capacities.

- difference between a patient*s self-appraisal about their driving skills, a companion's appraisal, and the performance on the simulator and

neuropsychological assessments.

Study description

Background summary

Huntington*s disease (HD) is an autosomal dominant inherited neurodegenerative disorder that is characterized by a triad of symptoms including motor disturbances, cognitive dysfunction and psychiatric symptoms. Quality of life and functional ability are strongly affected by cognitive impairments. Occupational decline and inability to drive safely are most frequently reported by HD patients and companions. Driving requires multiple complex actions and optimal cognitive functioning, and is therefore challenging for patients with HD. However, studies on driving capacities in HD are still scarce and methods are heterogeneous. Premanifest gene carriers and early stage HD patients often have questions for the physician regarding their driving skills and are most likely in need of a driving evaluation in the near future, yet none of the research has evaluated fitness to drive in these groups.

Study objective

Primary objectives:
- To investigate possible differences in driving performances between premanifest gene carriers, manifest HD, and control subjects.
- To explore if different aspects of cognitive functioning might be a predictor of fitness to drive in HD gene carriers across multiple disease stages.
- To investigate the possible association between motor functioning and driving capacities.

Secondary objectives:
- To investigate the possible relationship between behavioural changes and driving capacities.
- To investigate if there is a relationship between a patient*s self-appraisal about their driving skills, companion appraisals, and the performance on the driving simulator and cognitive assessments.

Study design

This is a prospective, cross-sectional, observational study in HD gene carriers across multiple disease stages and healthy individuals who are not at risk for HD.

Study burden and risks

This is an observational study without any intervention, so there are no specific risks for the participants. The burden is limited to a minimum. All the assessments are performed during one visit.

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

All eligible subjects must meet the following inclusion criteria:
- be at least 18 years of age;
- possess a valid Dutch driver's licence;
- driven at least 300 km in the 12 months prior to study entry, to ensure regular driving activity.;Additional inclusion criteria HD manifest subjects
- confirmed CAG expansion of *36 in the HTT gene;
- UHDRS TMS >5.;Additional inclusion criteria for HD premanifest gene carriers

- confirmed CAG expansion of *36 in the HTT gene;
- UHDRS TMS *5, and no diagnosis in any other HD related domain (i.e. cognition or psychiatric).;Additional inclusion criteria for control subjects
- Gene negative for HD or no family history of HD, preferably spouses or relatives of HD subjects.

Exclusion criteria

All eligible subjects must meet none of the following exclusion criteria:
- Major comorbidities that are unrelated to HD (i.e. isolated psychiatric disorder, other neurological disorder, paralysis, ophthalmic disorder);
- Drug use (i.e. not medication) in the past 3 till 4 weeks prior to the visit day;
- Alcohol abuse (i.e. 3 or more glasses per day);
- Participation in intervention/clinical trials;
- Any other condition that in the opinion of the investigator warrants exclusion of the study.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2016
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-07-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	05-10-2016
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	NL55414.058.15