Validation of the Sustained Attention to Response Task (SART) for assessing the fitness to drive in narcolepsy and idiopathic hypersomnia patients

Published: 10-06-2015
Last updated: 21-04-2024

Primary aim is to validate the SART as a screenings instrument for driver fitness in patients with narcolepsy and idiopathic hypersomnia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON44358

Source
ToetsingOnline

Brief title
SART and driving fitness in narcolepsy and idiopathic hypersomnia

Condition

- Sleep disturbances (incl subtypes)

Synonym
idiopathic hypersomnia, Narcolepsy

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieu (VROM)
Source(s) of monetary or material Support: Ministerie van Infrastructuur en Milieu

Intervention

Keyword: Driving fitness, Idiopathic hypersomnia, Narcolepsy, Sustained Attention to Response Task

Outcome measures

Primary outcome

The primary endpoints of the study are, for the MWT: sleep latency, for the

SART: error scores and for the on-the-road driving test: standard deviation of

lateral position (SDLP).

Secondary outcome

The secondary endpoints of the study are:

- skin temperature measured with iButtons (sensors)

- eye blinks measured with electro-oculogram (EOG)

- subjective sleepiness measured with multiple questionnaires

- subjective driving quality measured with a visual analogue scale

- subjective driving effort measured with a visual analogue scale

Study description

Background summary

Excessive daytime sleepiness (EDS) is a core symptom of narcolepsy and idiopathic hypersomnia (IH). Sleepiness at the wheel obviously negatively impacts driving performance. Therefore, assessing the fitness to drive is formally required in individuals with EDS. The assessment is intended to determine patient*s ability to stay alert while driving. For this, the Maintenance of Wakefulness Test (MWT) is adopted by Dutch government in the assessment of driving fitness in narcolepsy and IH. However, the MWT is time consuming, labor-intensive and therefore too expensive compared to legal price limits for driving fitness assessments . Recent studies suggest that the Sustained Attention to Response Task (SART), a brief, computerized task, is a promising alternative to detect impaired vigilance in narcolepsy and IH. If

SART results correspond to MWT results, the SART might be a more cost effective alternative than the MWT in the evaluation of fitness to drive in narcolepsy and IH patients. Moreover, comparing the SART with on-the-road driving performance will further support its use.

Study objective

Primary aim is to validate the SART as a screenings instrument for driver fitness in patients with narcolepsy and idiopathic hypersomnia.

Study design

The study consists of two parts. In the primary part of the study (part 1) the outcomes of the SART will be compared to the outcomes of the MWT in a group of narcolepsy and IH patients being evaluated for fitness to driving. In the secondary part of the study (part 2) MWT and SART outcomes will be compared to those of an on-the-road driving test in a subset of patients.

Study burden and risks

Participation in the primary part of the study comprises one visit to a sleep clinic for a regular assessment of fitness to drive using the MWT, extended with four assessments of their performance in the SART and measurement of skin temperature. No complications of the SART are expected. Duration of this visit is approximately 8 hours. Participants are not financially rewarded for participation, except for receiving a free driving fitness assessment. Participation in the secondary part of the study comprises one visit to Maastricht University for performance measurement using a standardized on-the-road driving test, the SART, and a psychomotor vigilance task. During the driving test skin temperature will be measured. Duration of this visit is approximately 6 hours. Participants will be compensated for travelling expenses and will be financially rewarded with a ¤50 cheque . The on-the-road driving task is not expected to cause any substantial risk to the patient, apart from risks that are inherent to motorized traffic. Safety during the highway driving task is ensured by a licensed driving instructor accompanying the participant. The instructor has access to dual controls and can take over driving when he feels the participant is too drowsy to continue safely.

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

1. A diagnosis of narcolepsy with or without cataplexy or a diagnosis of idiopathic hypersomnia according to ICSD-3 criteria (AASM 2014)
2. If medication is used, stable treatment within 6 weeks prior to testing is required.
3. Aged 18 years or above.

Exclusion criteria

1. Presence of other indications/medical disorders that require a driver fitness test (Regeling Eisen Geschiktheid, 2000).
2. Insufficient mastery of Dutch language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2015
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	10-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL50579.068.14