An exploratory single-centre cross-over study in healthy subjects to investigate the effects of sleep deprivation on driving, EEG, and PainCart.

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Part A• To assess the effect of sleep deprivation on next morning driving (both on road and in simulated driving) and subjective self-reported driving performance tests;• To assess the effect of sleep deprivation on CNS functioning using the…

Ethical review	Approved WMO
Status	Completed
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON48420

Source
ToetsingOnline

Brief title
Effects of sleep deprivation on driving, cognition, EEG, and PainCart.

Condition

- Sleep disturbances (incl subtypes)

Synonym
insomnia, sleep deprivation

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research

Source(s) of monetary or material Support: Not Applicable;self funded CHDR study

Intervention

Keyword: cognition, driving, pain thresholds, sleep deprivation

Outcome measures

Primary outcome

Safety and tolerability endpoints

Part A, B and C

The safety is judged by investigator assessment.

Pharmacodynamic endpoints

Part A

Simulated and on the road driving

• Standard deviation of lateral position (SDLP) (main parameter)

• Number of lane departures (e.g., crash risk)

• Mean speed (MS)

• Standard deviation of speed (SDS)

• Perceived driving quality scale and perceived effort scale

• Driving quality scale by driving instructor

• Car driving exploratory biomarkers (drive safety score, head movements,

steering wheel)

Questionnaires

• Leeds Sleep Evaluation Questionnaire (LSEQ)

• Karolinska sleepiness scale (KSS)

NeuroCart

Adaptive tracking

• Average performance on adaptive tracking CFB (%)

Body Sway

• Total antero-posterior sway (mm)

Eye movements

• percentage time the subjects eyes are in smooth pursuit of the target during

smooth pursuit

VAS Bond and Lader

• Composite scores for alertness (mm)

Part B

NeuroCart

Adaptive tracking

• Average performance on adaptive tracking CFB (%)

Body Sway

• Total antero-posterior sway (mm)

Eye movements

• percentage time the subjects eyes are in smooth pursuit of the target during

smooth pursuit

VAS Bond and Lader

• Composite scores for alertness (mm)

Resting-EEG

• Frequency band power (Hz)

EEG in combination with auditory steady-state response

• The average inter-trial phase coherence between 35 and 45 Hz and between 200 and 500 ms

• The average evoked power between 35 and 45 Hz and between 200 and 500 ms

EEG in combination with Oddball tasks

• P300 and MMN amplitudes (µV) and latencies (msec)

EEG in combination with visual evoked potentials (VEP)

• N75 and P100 amplitudes (µV) and latencies (msec)

Part B and C:

Questionnaires

• Leeds Sleep Evaluation Questionnaire (LSEQ)

• Karolinska sleepiness scale (KSS

EEG in combination with laser-evoked potentials (LEP)

• Amplitude (µV) and latency (ms) of LEPs (N2, P2, and N2P2)

PainCart

• Heat Pain: Pain Detection Threshold (PDT) (°C)

• Electrical Burst: PDT (mA), Pain Tolerance Threshold (PTT) (mA), Area Under the VAS pain Curve (AUC) (mA*mm), and post-test VAS (mm).

• Electrical Stair (pre-cold pressor): PDT (mA), PTT (mA), Area Under the VAS pain Curve (AUC) (mA*mm), and post-test VAS (mm).

• Electrical Stair (post-cold pressor): PDT (mA), PTT (mA), AUC (mA*mm), and post-test VAS (mm).

• Conditioned Pain Modulation Response (change from electrical stair pre- and post-cold pressor): PDT (mA), PTT (mA), AUC (mA*mm).

• Pressure Pain: PDT (kPa), PTT (kPa), AUC (kPa*mm), and post-test VAS (mm).

• Cold Pressor: PDT (s), PTT (s), Area Above the VAS pain Curve (AAC) (s*mm), and post-test VAS (mm).

• Laser-evoked potentials: Subjective pain perception after LS (LS-NRS): Numeric rating scale (0-10 with 0=no pain & 10=worst pain imaginable)

• McGill Pain Questionnaire for each individual test

Intra-epidermal electrical stimulation

• Characteristics of the psychophysical curve: nociceptive detection threshold and slope (A50 & β)

• Intra-epidermal electrical stimulation evoked potentials (IESEP)

Secondary outcome

N.A.

Study description

Background summary

The assessment of potential sedative effects of new drugs is an important part of the early clinical drug development process. Undesired sedative drug effects may have important consequences, such as an increased risk of traffic accidents. Various methods are used to quantify sedative drug effects. This study assesses the sensitivity of additional measures of sedation, including driving behaviour and brain responses to various sensory and cognitive tasks.

The Centre for Human Drug Research (CHDR) aims to further validate these methods by demonstrating that they can detect the effects of sleep deprivation. Additionally, sleep deprivation also affects the perception of pain (e.g., lower pain thresholds). In this study the effects of sleep deprivation on a battery of pain tests will also be determined.

Study objective

Part A
• To assess the effect of sleep deprivation on next morning driving (both on road and in simulated driving) and subjective self-reported driving performance tests;
• To assess the effect of sleep deprivation on CNS functioning using the NeuroCart, a CNS test battery;
• To establish the relationship between on-the-road driving, simulated driving, and NeuroCart performance;
• To estimate the repeatability of standard deviation of the lateral position (SDLP) (both on road and in simulated driving) at day time at two different time points after a regular night of sleep.

Part B
• To assess the effect of sleep deprivation on event related potentials and EEG
• To assess the effect of sleep deprivation on pain tolerance / pain detection threshold using the PainCart, a pain test battery;
• To investigate the effect of sleep deprivation on IES sensitivity and LEPs;
• To estimate the repeatability of IES and LEP at day time at two different time points after a regular night of sleep.

Part C
• To assess the effect of sleep deprivation on pain tolerance / pain detection threshold using the PainCart, a pain test battery;
• To investigate the effect of sleep deprivation on IES sensitivity and LEPs;
• To estimate the repeatability of IES and LEP at day time at two different time points after a regular night of sleep.

Study design

An exploratory single-centre cross-over study in healthy subjects.

Intervention

Sleep deprivation

Study burden and risks

There is no benefit for the subjects in this study. The risk of the

intervention is negligible. For the on-the-road test are safety precautions taken: a driving instructor has access to dual controls to intervene when needed for safety reasons and the subject is instructed about the possibility to stop the driving test before the planned ending.

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

Male (part A and B) or female (part C only)
Age between 23 and 35
At least 3 years in possession of a drivers license (only part A).
At least 3000 km/y driving experience over the last 3 years. (only part A).

Exclusion criteria

Presence of psychiatric illness
Drug abuse in medical history
Sleep disorder
Pain disorder (including chronic)
Only for part B and C: dark skin type (Fitzpatrick V-VI)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-02-2019
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-02-2019
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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: 24188
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68626.056.19

Study results

Date completed:	17-02-2021
Results posted:	08-02-2023

First publication
04-08-2022