Study into the effects of sleep deprivation on driving, cognitive ability and pain perception

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24188

Source
Nationaal Trial Register

Brief title
CHDR1818

Health condition

Sleep disorders

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: N.A., CHDR funded study

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Not applicable

Study description

Background summary

Effects of sleep deprivation on driving, EEG, and PainCart. Single center study, (Centre For Human Drug Research) in Leiden, The Netherlands

Study objective

Sleep deprivation induces impaired driving behavior, decreased cognitive function and lower pain thresholds

Study design

Approximately 9:00 in the morning and 14:00 in the afternoon

Intervention

Sleep deprivation

Contacts

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Eligibility criteria

Inclusion criteria

• Healthy subjects, aged 23 to 35 years, inclusive; healthy is defined as no clinically relevant abnormalities identified by a detailed medical and surgical history and a complete physical examination including vital signs. For part A and B: males only, for part C: females only.
• Body mass index (BMI) between 18 and 32 kg/m2 inclusive.
• Subjects are active and experienced drivers (applicable for part A only):
o In possession of a driver’s license, minimum driving experience of 5 years or more.
o Minimal car driving mileage of 3000 km per year during the past three years.
• Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

- History or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic or renal disorder.
- Positive test for drugs of abuse at screening or during the study. Positive tests at screening may be repeated.
- History of and presence of sleep disturbances/disorders.
- Change in time zones 7 days prior to the study periods.
- Smoker of more than 10 cigarettes per day prior to screening or who use tobacco products equivalent to more than 10 cigarettes per day.
- Consume, on average, > 8 units/day of (methyl)-xanthines (e.g. coffee, tea, cola, chocolate)

and not able to refrain from use during each stay at the CHDR clinic.
- Presence of Simulator Sickness Syndrome (applicable for part A only).
- Subjects indicating pain tests intolerable at screening or achieving tolerance at >80% of maximum input intensity for any pain test for cold, pressure and electrical tests (applicable for part B and C only).
- Any circumstances or conditions, which, in the opinion of the investigator, may affect full participation in the study or compliance with the protocol.
- Dark skin (Fitzpatrick skin type V - VI), wide-spread acne, tattoos or scarring on the volar forearms (applicable for part B and C only).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2019
Enrollment:	72
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48420
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7517
CCMO	NL68626.056.19
OMON	NL-OMON48420

Study results