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

No registrations found.

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|---|---|
| **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

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | N/A: single arm study |
| 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

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|---|---|
| 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