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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24188

Bron
Nationaal Trial Register

Verkorte titel
CHDR1818

Aandoening

Sleep disorders

Ondersteuning

Primaire sponsor: Centre for Human Drug Research
Overige ondersteuning: N.A., CHDR funded study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Sleep deprivation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-02-2019
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-02-2019

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48420
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten