VR-PainCart pilot

Gepubliceerd: 14-04-2021 Laatst bijgewerkt: 15-05-2024

To assess the effect of Virtual Reality mediated visual and auditory lowering of electrical pain detection and tolerance thresholds.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28178

Bron
Nationaal Trial Register

Verkorte titel
CHDR2037

Aandoening

Pain

Ondersteuning

Primaire sponsor: Centre for Human Drug Research
Overige ondersteuning: Centre for Human Drug Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Electrical Stair: PDT (mA), PTT (mA), Area Under the VAS pain Curve (AUC) (mA*mm).
• Electrical Stair (including virtual reality simulation without enhancement): PDT (mA), PTT (mA), Area Under the VAS pain Curve
(AUC) (mA*mm).
• Electrical Stair (including virtual reality simulation with enhancement): PDT (mA), PTT (mA),

Area Under the VAS pain Curve (AUC) (mA*mm).

Toelichting onderzoek

Achtergrond van het onderzoek

The VR simulation is added to a nociceptive pain measurement, the electrical stair test from the PainCart®. The PainCart® has been proven sensitive in clinical trials in detecting the pharmacodynamic effects of multiple analgesics. The measurements are performed in a quiet room, each subject is assigned to a separate room to minimize any distraction. The electrical stair test uses two electrodes on the tibial bone to assess cutaneous electrical pain. Single electrical stimuli are provided with a duration of 0.2 ms, increasing from 0 mA to a maximum of 50 mA in steps of 0.5 mA. The maximum duration of the test is 120 seconds.
In this study a VR simulation is introduced aimed at enhancing the pain perception. Two VR environments (VR-neutral and VR+) are developed, both simulating a room with a PainCart setup. The environments include an avatar of the subject, the chair, and equipment of the electrical stair pain test, including electrodes on the leg and a VAS slider. The VR-neutral simulation has no additional aspects; it shows a similar setup as the test without VR. During the VR+ simulation, a wound appears simultaneously with the intensity of the pain test. The visual enhancement is supported with accompanying sounds of electrical sparks. The simulation of the wounds starts and stops simultaneously with the stimulation, both controlled by the subject. After 40 seconds of simulation the intensity of the audio-visual stimulation no longer increases. The VAS slider is visible in the simulation and used to record the Pain Detection Threshold (PDT) and Pain Tolerance Threshold (PTT).

Doel van het onderzoek

To assess the effect of Virtual Reality mediated visual and auditory lowering of electrical pain detection and tolerance thresholds.

Onderzoeksopzet

Screening up to -90 days till EOS

Onderzoeksproduct en/of interventie

Virtual Reality images

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Healthy male subjects aged 18-40 years, inclusive; healthy is defined as no clinically relevant abnormalities identified.
• 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 of symptoms or any significant including (but not limited to) neurological or psychiatric disorder., if assessed by the Principal Investigator as possibly interfering with the study objectives.
• High pain tolerance (80% or higher value for the pain tolerance of the electrical stair test)
• Presence of Virtual Reality Sickness (simulator sickness).
• Smoker of more than 5 cigarettes per day prior to screening or who use tobacco products equivalent to more than 5 cigarettes per day.
• Consume, on average, > 8 units/day of (methyl)-xanthines (e.g. coffee, tea, cola, chocolate) or not able to refrain from use during each stay at the CHDR clinic.
• Have a urine drug screen detecting illicit drug of abuse (morphine, benzodiazepines, cocaine, amphetamine, THC, methamphetamines, MDMA) or a positive alcohol breath test;

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-03-2021
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	14-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50817
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9398
CCMO	NL75934.056.20
OMON	NL-OMON50817

Resultaten

Samenvatting resultaten
N.A.