VR-PainCart pilot

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28178

Source
Nationaal Trial Register

Brief title
CHDR2037

Health condition

Pain

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Centre for Human Drug Research

Intervention

Outcome measures

Primary outcome

• 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).

Secondary outcome

Questionnaires on personal characteristics, stress, anxiety and the relationship with electrial pain detection and tolerance thresholds.

Study description

Background summary

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).

Study objective

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

Study design

Screening up to -90 days till EOS

Intervention

Virtual Reality images

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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;

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	14-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50817
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N.A.