Evaluating the effect of zolpidem and suvorexant on walking ability.

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• To assess effect of zolpidem compared to placebo on walking (adapt)ability in healthy elderly as measured by the Interactive Walkway. • To assess effect of suvorexant compared to placebo on walking (adapt)ability in healthy elderly as measured by...

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

Samenvatting

ID

NL-OMON25974

Bron
Nationaal Trial Register

Verkorte titel
CHDR2040

Aandoening

walking (adapt)ability, risk of falling

Ondersteuning

Primaire sponsor: CHDR
Overige ondersteuning: CHDR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pharmacodynamic endpoints
The Interactive Walkway takes approximately 15 minutes and includes the following tests:

• 8-meter walking test. Walking at a self-selected walking speed. The outcome measures are walking speed (cm/s), step length (cm),step width (cm), cadence (steps/min), and step time (s). The test has a duration of approximately 1-2 minutes.
• Obstacle avoidance. Avoiding suddenly appearing obstacles. The outcome measures are obstacle-avoidance margins (cm), successrate (%), and (normalized) walking speed (%). The test has a duration of approximately 4-5 minutes.
• Goal-directed stepping. Stepping as accurately as possible onto the shoe-size-matched steppingstones placed in an irregular pattern. The outcome measures are stepping accuracy (cm) and (normalized) walking speed (%). The test has a duration of approximately 1-2minutes.
• Tandem walking. Walking on a line. The outcome measures are success rate (%), (normalized) walking speed (%), and mediolateralsway (cm). The test has a duration of approximately 1-2 minutes.
• Timed Up-and-Go test. Rising from a standard armchair, walking to a line on the floor 3 meters away, turning, returning, and sitting down again. The outcome measures is time (s). The test has a duration of approximately 3-4 minutes.

The NeuroCart for this study includes the following tests:
• Body Sway. This test assesses postural stability. The outcome measure is sway (mm). The test has a duration of approximately 2minutes.
• Adaptive Tracker. This test assesses pursuit-tracking. The outcome measure is success rate (%) The test has a duration of approximately 3 minutes.

The Withings Steel HR smartwatch includes the following tests:
• Step count
• Heart rate
• Sleep pattern (time it takes to fall asleep, sleep duration, sleep cycles and sleep interruptions)
• Physical activity duration
Pharmacokinetic endpoints

PK parameters of suvorexant and zolpidem by non-compartmental analysis of the plasma concentration-time data:
Maximum concentration (Cmax), Time to attain Cmax (Tmax), Area under the concentration – time curve (AUClast), TerminalElimination Half-life (t1/2).

Tolerability and safety endpoints
Adverse events and vital signs measurements.

Toelichting onderzoek

Achtergrond van het onderzoek

Dynamic assessments like walking adaptability may yield a stronger predictor for falls, as falls predominantly occur during walking and transfers that demand gait adjustment.

Previous studies have shown most walking-related falls result from inadequate interactions with environmental context, leading to balance loss due to a trip, slip or misplaced step14. Walking adaptability thus seems to be an important determinant of fall risk. The Interactive Walkway is an instrument developed to assess walking adaptability by augmenting a multi-Kinect-v2 10-m walkway with gait-dependent visual context (stepping targets, obstacles) using real-time processed markerless full-body kinematics15,16.Measurement of walking adaptability using the Interactive Walkway includes the ability to avoid obstacles, make sudden stops and starts and accurately place the feet to environmental context.

Doel van het onderzoek

• To assess effect of zolpidem compared to placebo on walking (adapt)ability in healthy elderly as measured by the Interactive Walkway.
• To assess effect of suvorexant compared to placebo on walking (adapt)ability in healthy elderly as measured by the Interactive Walkway.
• To compare the effect of suvorexant with the effect of zolpidem on walking (adapt)ability in the first three hours after drug administration.
• To explore the influence of smartwatch-based night-time sleep on Interactive Walkway and NeuroCart endpoints.
• To explore the validity of a smartwatch-based Timed Up and Go model.
• Optional. To establish the relationship between walking (adapt)ability parameters, Body Sway, and Adaptive Tracker.

Onderzoeksopzet

-21 days (Screening) till EOS

Onderzoeksproduct en/of interventie

Suvorexant 10 mg
Zolpidem 5 mg

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male and female subjects aged between 65 years and 80 years (inclusive) at screening.
2. Body mass index (BMI) within the range of 18 to 30 kg/m2 (inclusive) at screening.
3. Systolic blood pressure 100-160 mmHg, diastolic blood pressure 50-95 mmHg, and pulse rate 45-100 bpm(inclusive), measured on either arm, after 5 min in the supine position at screening.
4. Estimated creatinine clearance (using the Cockcroft &Gault formula) ≥60 mL/min to allow for some reduced renal function in the elderly.
5. Subject has a regular sleep pattern (bedtime between 22:00 and 00:30 and sleep for at least 6 h).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Hypersensitivity to benzodiazepines and/ or meeting contraindication criteria for zolpidem: myasthenia gravis, sleep apnea syndrome, liver failure, respiratory depression.
2. Hypersensitivity to orexin antagonist and/ or meeting contraindication criteria for suvorexant: narcolepsy.
3. Regular use of sedative/hypnotic drugs.
4. Regular use of walking aids.
5. Recurrent fallers defined as > 3 falls per year.
6. Neurological diseases and/or orthopedic problems interfering with gait function
7. Mini Mental State Examination score < 25 at Screening.
8. Current or previous diagnosis of insomnia-related disorder according to the Diagnostic and Statistical Manual of Mental Disorders version 5 (DSM-5) criteria.
9. Vaccination for SARS-CoV-2 within 4 days of screening and/or dosing with study drug.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	18
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:	21-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50820
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9528
CCMO	NL76600.056.21
OMON	NL-OMON50820

Resultaten

Samenvatting resultaten
N.A.