Evaluating the effect of zolpidem and suvorexant on walking ability.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25974

Source
Nationaal Trial Register

Brief title
CHDR2040

Health condition

walking (adapt)ability, risk of falling

Sponsors and support

Primary sponsor: CHDR
Source(s) of monetary or material Support: CHDR

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N.A.

Study description

Background summary

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.

Study objective

• 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.

Study design

-21 days (Screening) till EOS

Intervention

Suvorexant 10 mg
Zolpidem 5 mg

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2021
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	21-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50820
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9528

Register	ID
CCMO	NL76600.056.21
OMON	NL-OMON50820

Study results

Summary results

N.A.