A randomized, placebo-controlled, 2-way crossover, double-blind study to evaluate the efficacy, safety and tolerability of JNJ-42847922 in subjects with insomnia disorder without psychiatric comorbidity.

Published: 22-07-2015
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The purpose of this study is to see if JNJ-42847922 is useful for treating patients with insomnia without any other psychiatric disease. The safety of JNJ-42847922 will also be studied.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON42553

Source
ToetsingOnline

Brief title
JNJ-42847922 for insomnia without psychiatric comorbidity.

Condition

- Sleep disorders and disturbances

Synonym
Insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Clinical pharmacology, Insomnia

Outcome measures

Primary outcome

- Latency to persistent sleep (minutes)

- Total sleep time (minutes)

- Wake After Sleep Onset (minutes)

- Wake during total sleep period (minutes)

- Wake after final awakening (minutes)

- Sleep efficiency (%)

- Total time spent in deep sleep (duration of slow wave sleep) (minutes)

Secondary outcome

PSG secondary endpoints

- Time in bed (minutes)

- Sleep onset latency (minutes)

- Number of awakenings (#)

- Time to first awakening after sleep onset (minutes)

- REML (minutes)

- Duration of REM sleep (minutes)

- Duration of Stage 1 Sleep (minutes)

- Duration of Stage 2 Sleep (minutes)

- Number of REM blocs (#)

Safety

- ECG

- Vital signs

- Blood chemistry / hematology

Suicidal assessment by C-SSRS Questionnaire

Sleep questionnaires:

Bond and Lader Visual Analogue Scale

Karolinska Sleepiness Scale

Leeds Sleep Evaluation Questionnaire

Study description

Background summary

JNJ-42847922 is a potent and selective antagonist of the human orexin-2 receptor (OX2R) that is being developed for the treatment of insomnia and major depressive disorder (MDD). In rats, JNJ-42847922 quickly and reversibly binds to OX2R in the brain after oral administration and reduces sleep latency and increases total sleep duration whilst not affecting Rapid Eye Movement (REM) sleep. JNJ-42847922 induced dose-related somnolence in healthy subjects after daytime administration and decreased the latency to persistent sleep (LPS) and increased the total sleep time (TST) in MDD patients with insomnia after nighttime administration of a single dose of 10 mg or higher.

Study objective

The purpose of this study is to see if JNJ-42847922 is useful for treating patients with insomnia without any other psychiatric disease. The safety of

JNJ-42847922 will also be studied.

Study design

This study is a multi-center, randomized, placebo-controlled, double-blind, 2-way cross-over study with JNJ-42847922 in 26 healthy male and female subjects with insomnia disorder without psychiatric comorbidity.

Intervention

Subjects will receive during each study period one of the following treatments for 5 days once a day:
-40 mg JNJ-42847922
-placebo

Study burden and risks

Subjects will receive 40 mg JNJ-42847922 and placebo q.d. for 5 days in two treatment sequences. JNJ-42487922 has been administered to healthy male and female subjects for 10 days up to 60 mg [42847922EDI1003] and was well tolerated. JNJ-42847922 causes somnolence/sedation when administered at daytime. When administered in the evening, JNJ-42847922 increases SE, decreases LPS and increases TST [42847922EDI1002] at all doses tested (10, 20, and 40 mg). None of the doses tested significantly affected WASO or the number of awakenings in the latter study which may be related to study design (phase advanced sleep time), population (MDD), and the limited sample size.

A 40 mg JNJ-42847922 dose level is selected for this study because it has been demonstrated to be well tolerated, offers some slight benefit on sleep parameters versus a 20 mg dose level, and to optimize our ability to detect, if present, an effect on WASO.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male and female participants aged between 18 and 65 years, inclusive
- Body mass index (BMI) between 18 and 30 kilogram per square meters (kg/m^2) inclusive (BMI = weight/height^2)
- Insomnia Severity Index (ISI) score more than or equal to 15 at screening
- Insomnia: at screening participants will report both difficulties with sleep onset and sleep maintenance. Insomnia will furthermore objectively be established prior to enrollment per PSG recorded over 3 consecutive nights. Participants will sleep for 3 consecutive nights in the sleep center. First and second night data will be used to exclude any participant with restless leg syndrome, apnea, parasomnias or other sleepdisorders. On the second and third night participants are required to meet objective inclusion criteria: 2-night mean LPS of >= 30 minutes with no night < 20 minutes, and on both nights TST =< 6 hours and wake after sleep onset (WASO) >30 minutes
- Participants must be healthy /medically stable on the basis of clinical laboratory tests, medical history, vital signs, and 12-lead electrocardiogram (ECG) performed at screening and baseline

Exclusion criteria

Participant has current signs/symptoms of, liver or renal insufficiency; hypothyroidism or hyperthyroidism, significant cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic, or metabolic disturbances. Participants with non-insulin dependent diabetes mellitus who are adequately controlled (not on insulin) may participate in the study
- History of epilepsy or fits or unexplained black-outs

- Clinically significant abnormal values for hematology, clinical chemistry or urinalysis at screening or admission
- Clinically significant abnormal physical and neurological examination, vital signs or 12-lead ECG at screening or baseline
- Smoking >10 cigarettes/daily
- Insomnia related to restless leg syndrome, sleep breathing disorder, narcolepsy, obstructive sleep apnea/hypopnea, central sleep apnea, sleep-related hypoventilation, circadian rhythm sleep-wake disorders, substance/medication-induced sleep disorder or parasomnias
- Night-shift worker or significantly shifted diurnal activity pattern

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2015
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	JNJ-42847922
Generic name:	JNJ-42847922

Ethics review

Approved WMO Date:	22-07-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-07-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-10-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-11-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-001672-22-NL
CCMO	NL54083.056.15