A Randomized, Double-Blind, Placebo-Controlled, Crossover On-Road Driving Study Assessing the Effect of JZP-110 on Driving Performance in Subjects with Excessive Sleepiness Due to Obstructive Sleep Apnea

Published: 15-02-2016
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Primary objective:- To evaluate the effect of JZP-110 on driving performanceSecondary objectives:- To evaluate the safety and tolerability of JZP-110- To explore SAFTE (Sleep, Activity, Fatigue, and Task Effectiveness) modeling using driving,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON47629

Source
ToetsingOnline

Brief title
Effect of JZP-110 on driving performance in subjects with sleep apnea

Condition

- Sleep disturbances (incl subtypes)

Synonym
Obstructive sleep apnea; temporary respiratory arrest

Research involving

Human

Sponsors and support

Primary sponsor: JAZZ Pharmaceuticals Inc.
Source(s) of monetary or material Support: JAZZ Pharmaceuticals

Intervention

Keyword: driving performance, JZP-110, obstructive sleep apnea

Outcome measures

Primary outcome

Standard deviation of lateral position (SDLP) at 2 hours post-dose

(approximately at Tmax)

Secondary outcome

* SDLP at 6 hr post-dose

* Proportion of subjects with improved or impaired driving on JZP-110 compared

to placebo

* Standard deviation of Speed (SDS)

* Driving lapses

* PVT measures

* Inverse reaction time (1/RT)

* Lapses (RT>500 ms)

* Mean reaction time (RT)

* Errors of commission

* Toronto Hospital Alertness Test (THAT)

Study description

Background summary

JZP-110 is a phenylalanine derivative that is currently being investigated as a potential treatment for excessive
sleepiness in narcolepsy and obstructive sleep apnea (OSA).

Patients with OSA are known to have impaired driving performance due to drowsiness. This study is designed to assess effects of JZP-110 on driving performance in patients with OSA. In addition, it is also of interest to assess the effects of JZP-110 on measures of attention, response time, and risk-taking or impulsivity. In this study, the psychomotor vigilance test (PVT) will be used to assess psychomotor performance, with errors of commission on the PVT as a measure of impulsivity.

Study objective

Primary objective:
- To evaluate the effect of JZP-110 on driving performance

Secondary objectives:
- To evaluate the safety and tolerability of JZP-110
- To explore SAFTE (Sleep, Activity, Fatigue, and Task Effectiveness) modeling using driving, Psychomotor Vigilance
Test (PVT) and sleep data

Study design

This trial is a randomized, double-blind, placebo-controlled, crossover study.

Subjects will be recruited at sleep clinics or Clinical Sites. Eligibility will be determined through screening procedures including a Maintenance of Wakefulness Test (MWT) after the washout of prohibited medications at Clinical Sites and a practice driving test at the Driving Test Site. Eligible subjects will be randomized to receive either JZP-110 (150 mg/day for 3 days, followed by 300 mg/day for 4 days) or the matching placebo for 7 days, and will then crossover to receive the other treatment for 7 days. On Day 7 of each treatment period, all randomized subjects will have a study visit to undergo two driving performance tests, one at 2 hours (between 1 to 3 hours) and the other at 6 hours (between 5 to 7 hours) after the morning dose.

The Psychomotor Vigilance Test (PVT) will be administered at pre-dose and prior to each driving test. Actigraphy and a sleep diary will be used to assess daily sleep patterns. The Toronto Hospital Alertness Test (THAT) will be administered

at baseline and the end of each treatment period. A follow-up visit will be performed approximately 7 days after the final dose of study drug. The initial two screening visits, including MWT assessment, and the follow-up visit will be conducted at the Clinical Sites and the remaining Baseline visit and two driving assessment visits will be conducted at the Driving Test Site. Safety will be assessed throughout the study. Screening procedures will include physical examination, electrocardiogram (ECG), and clinical laboratory tests. A physical examination will be performed at completion of the study or at early termination and adverse events will be collected and assessed throughout the study. The Columbia- Suicide Severity Rating Scale (C-SSRS) will be completed at screening and each visit.

Intervention

7 days of JZP-110 (150 mg/day for 3 days, followed by 300 mg/day for 4 days) and 7 days of placebo in counterbalanced order

Study burden and risks

- As in any study with a new drug known or (still) unknown side effects can manifest themselves
- Very low risk of an accident while conducting the driving test (instructor sits beside the patient during driving test)
- Depending on the drug that the patient is already using for the treatment of narcolepsy it may be necessary that one stops the use of these, before one can start with the intake of the study medication. Phasing out of the existing medications could theoretically lead to risk. However, only a small proportion of patients will have to reduce medication and patients in which in advance it is estimated that this will pose a risk, will not be approached for the study.
- During their participation in the study, participants must wear an actigraph.
- Participants have to complete a sleep diary during their complete participation in the study. Furthermore they have to keep track of when they use their usual OSA treatment (sleep mask or dental prosthesis).
- During participation in the study subjects can possibly not drive a car by themselves (i.e. from the time that the own medication, if any, will be phased out until the last intake of study medication. Whether or not a subject is able to continue driving during participation is determined by his/her physician and discussed with him/her.

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

- Male or female, age 21 to 75 years inclusive
- Diagnosis of obstructive sleep apnea (OSA) per ICSD-3 criteria
- BMI 18 to <40 kg/m2
- Use a medically acceptable method of contraception
- Willing and able of provide written informed consent

Exclusion criteria

- Female subjects who are pregnant, nursing, or lactating
- Any other clinically relevant medical, behavioral, or psychiatric disorder other than OSA that is associated with excessive sleepiness
- History or presence of bipolar disorder, bipolar related disorders, schizophrenia, schizophrenia spectrum disorders, or other psychotic disorders according to DSM-5 criteria
- History or presence of any unstable medical condition, behavioral or psychiatric disorder (including active suicidal ideation), or surgical history that could affect the safety of the subject or interfere with study efficacy

and/or safety assessments per the judgment of the investigator
- History of bariatric surgery within the past year
- Presence of significant cardiovascular disease
- Use of any over-the-counter (OTC) or prescription medications that could affect sleep-wake function

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	JZP-110
Generic name:	Solriamfetol

Ethics review

Approved WMO

Date:	15-02-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-05-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-11-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-11-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-07-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-09-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-09-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-06-2019

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2015-003930-28-NL
CCMO	NL56214.068.16
Other	nog niet beschikbaar