An open-label, randomized crossover study to evaluate the pharmacokinetics, bioavailability, bioequivalence, and food effect following administration of Oxybate Formulations in healthy subjects.

Published: 14-07-2014
Last updated: 21-04-2024

Primary Objectives:Part 1:To assess the relative bioavailability and bioequivalence of JZP-258 compared with Xyrem oral solution under fasting and fed conditions.To evaluate the pharmacokinetics (PK) of JZP-258 under fasting and fed conditions (food...

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

Summary

ID

NL-OMON41817

Source
ToetsingOnline

Brief title
JZP-258 Oxybate BA and FE study.

Condition

- Sleep disturbances (incl subtypes)

Synonym
narcolepsy, sleeping disorder

Research involving

Human

Sponsors and support

Primary sponsor: Jazz Pharmaceuticals
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Narcolepsy, oxybate formulations, Xyrem

Outcome measures

Primary outcome

Primary Objectives:

To assess the relative bioavailability and bioequivalence of JZP-258 compared

with Xyrem oral solution under fasting and fed conditions.

To evaluate the pharmacokinetics (PK) of JZP-258 under fasting and fed

conditions (food effect).

Secondary outcome

Secondary Objective:

To assess the safety and tolerability of JZP-258 and Xyrem under fasting and

fed conditions.

Study description

Background summary

JZP-258 is a new investigational compound that may eventually be used for the treatment of narcolepsy. Narcolepsy is a sleeping disorder that involves excessive daytime sleepiness, and in some people, a sudden loss of muscle tone usually triggered by strong emotion.
JZP-258 is an oral oxybate formulation that is being compared to Xyrem.

Study objective

Primary Objectives:
Part 1:
To assess the relative bioavailability and bioequivalence of JZP-258 compared with Xyrem oral solution under fasting and fed conditions.
To evaluate the pharmacokinetics (PK) of JZP-258 under fasting and fed conditions (food effect).
Part 2:
To evaluate the relative bioavailability and bioequivalence of two admixtures of JZP-258 and Xyrem at different ratios compared with Xyrem oral solution under fasting conditions
To evaluate the pharmacokinetics (PK) of JZP-258 2.25 g under fasting conditions

Secondary Objective:
Part 1:
To assess the safety and tolerability of JZP-258 and Xyrem under fasting and fed conditions.
Part 2:
To assess the safety and tolerability of two admixtures of JZP-258 and Xyrem at different ratios under fasting conditions.

Study design

This study will be performed in a group of approximately 60 healthy male or female volunteers.
The volunteers will receive 4 treatments in which either JZP-258 or Xyrem will be administered with or without food.
Each period the volunteers will receive a solution of 4.5 g JZP-258 or Xyrem, diluted in 60 mL of water, taken with 180 mL of tap water.
In Part 2, two admixtures of JZP-258 and Xyrem in different ratios will be compared with Xyrem under fasting conditions. The PK of JZP-258 at a lower dose of 2.25 g will also be evaluated under fasting conditions.

Intervention

The study consists of 4 treatments in which either JZP-258 or Xyrem will be administered with or without food. The order in which the volunteers will receive the treatments will be determined by chance. Please refer to the table below to see the planned treatments:

Part 1:
Treatment How often
A 4.5 g JZP-258 Once, 10 hours fasted
B 4.5 g JZP-258 Once, 10 hours fasted
C 4.5 g Xyrem Once, 10 hours fasted
D 4.5 g Xyrem Once, 10 hours fasted

Part 2:

E: Admixture of 4.5 g JZP-258 and Xyrem diluted in 60 mL of water, taken with 180 mL water, under fasting conditions
F: Admixture of 4.5 g JZP-258 and Xyrem diluted in 60 mL of water, taken with 180 mL water, under fasting conditions,
G: 4.5 g Xyrem, diluted in 60 mL of water, taken with 180 mL water, under fasting conditions
H: 2.25 g JZP-258, diluted in 60 mL of water, taken with 180 mL (6 fluid ounces) of water, under fasting conditions

Study burden and risks

During the study various examinations are carried out that can be experienced more or less stressful.
Blood sampling, indwelling cannula, heart tracing (ECG), pulse oximetry

Contacts

Public
Jazz Pharmaceuticals

Porter Drive 3180
Palo Alto CA 94304
US
Scientific
Jazz Pharmaceuticals

Porter Drive 3180
Palo Alto CA 94304
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy male or female volunteers
18 - 45 years, inclusive
BMI 18-30 kg/m2, inclusive
non smoking

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2014
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Xyrem
Generic name:	Sodium Oxybate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-01-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-02-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-02-2015
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	EUCTR2014□002469□32-NL
CCMO	NL49177.056.14