Study to evaluate the pharmacokinetics of oxybate formulations in healthy subjects.

Published: 01-06-2016
Last updated: 14-04-2024

The purpose of the study is to investigate how much JZP-258 is absorbed into the body, how fast JZP-258 is absorbed and eliminated from the body (this is called pharmacokinetics) compared to Xyrem. This comparison is called the relative...

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

Summary

ID

NL-OMON43010

Source
ToetsingOnline

Brief title
JZP-258 PK Study

Condition

- Sleep disturbances (incl subtypes)

Synonym
cataplexy, narcolepsy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Oxybate formulations

Outcome measures

Primary outcome

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

solution versus Xyrem taken with 60 mL water under fasting conditions.

Secondary outcome

To assess the effect of food on pharmacokinetics (PK) of JZP-258 oral solution

and Xyrem taken with 60 mL water

To assess the safety and tolerability of JZP-258 oral solution and Xyrem

administered under all dosing conditions in this study

Study description

Background summary

JZP-258 is an investigational compound that is being evaluated for the treatment of cataplexy in subjects with narcolepsy. Narcolepsy is a sleeping disorder that involves excessive daytime sleepiness and, in some patients, a sudden loss of muscle tone usually triggered by strong emotion (cataplexy). JZP-258 is not an approved drug product, but it has been tested in humans in other research studies. JZP-258 is a low-salt version of the approved product Xyrem® (sodium oxybate) marketed worldwide for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy. JZP-258 and Xyrem contain the same active ingredient (oxybate) and are oral solutions. This study will compare the results of the JZP-258 study compound to the results of Xyrem study compound.

Study objective

The purpose of the study is to investigate how much JZP-258 is absorbed into the body, how fast JZP-258 is absorbed and eliminated from the body (this is called pharmacokinetics) compared to Xyrem. This comparison is called the relative bioavailability. In addition, it will be investigated if the

pharmacokinetics of JZP-258 are similar to Xyrem. This comparison is called the bioequivalence. Subjects will receive both JZP-258 and Xyrem in this study so that the results can be compared within each subject. Also, the effect of food and different amounts of water taken with the study compound on the pharmacokinetics of JZP-258 and Xyrem will be investigated. The safety and tolerability of JZP-258 will also be carefully monitored throughout this study.

Study design

Day 1 is the first day of administration of study compound (JZP-258 or Xyrem). The volunteers are expected at the clinical research center at 14:00 h in the afternoon prior to the day of first administration of the study compound. They will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).

Each treatment with JZP-258 or Xyrem is separated by a period of 1 day. They will receive JZP-258 or Xyrem on Days 1, 3, 5, 7, 9 and 11. During the study they will stay for 13 days (12 nights: from Day -1 to Day 12) in the clinical research center.

On the final study day (Day 12) they will undergo a post study evaluation, during which they will get similar examinations as in the pre-study screening. If the participation in the study is ended earlier than Day 12 for any reason, they will be asked to undergo the post-study evaluations to check on their safety and to complete any final tests.

The participation in the entire study, from the pre-study screening until the post study evaluations, will be maximally 33 days.

Intervention

Treatment A: 4.5 g JZP-258 taken with 60 mL water under fasting conditions, once
Treatment B: 4.5 g Xyrem taken with 60 mL water under fasting conditions, once
Treatment C: 4.5 g JZP-258 taken with 60 mL water under fed conditions, once
Treatment D: 4.5 g Xyrem taken with 60 mL water under fed conditions, once
Treatment E: 4.5 g Xyrem taken with 240 mL water under fasting conditions, once
Treatment F: 4.5 g JZP-258 taken with 240 mL water under fasting conditions, once

Study burden and risks

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

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 Caucasion volunteers
18-45 years, inclusive
BMI 20-30 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):	14-06-2016
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:	01-06-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-06-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	01-09-2016
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	EUCTR2016-001775-69-NL
CCMO	NL57960.056.16