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

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

Summary

ID

NL-OMON43111

Source
ToetsingOnline

Brief title
KEY-507 PK, BA and BE Study

Condition

- Sleep disturbances (incl subtypes)

Synonym
narcolepsy, sleeping disorder

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Narcolepsy, Oxybate formulations, Xyrem

Outcome measures

Primary outcome

To assess the relative bioavailability and bioequivalence of the four KEY-507

oral solutions compared with Xyrem under fasting conditions.

Secondary outcome

To assess the safety and tolerability of the four KEY-507 oral solutions and

Xyrem under fasting conditions

To assess the palatability of the taste of the four KEY-507 oral solutions and

Xyrem under fasting conditions

Study description

Background summary

KEY-507 oral solutions are new investigational compounds that are being evaluated 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 (cataplexy). One of the current medications for excessive daytime sleepiness and cataplexy in narcolepsy is Xyrem® (sodium oxybate, also known as the sodium salt of gamma-hydroxybutyric acid [GHB]). This is an oral solution that contains a high amount of sodium at the highest approved dose. Sodium oxybate/GHB is a substance that has depressant or sedating effects in people.
KEY-507 are 4 new oral solutions that contain the same active substance as Xyrem, but reduce the daily intake of sodium. This is the first time that

KEY-507 oral solutions are being given to humans.

Study objective

During the study, the 4 KEY-507 oral solutions (KEY-507-A, KEY-507-G, KEY-507-C, and KEY 507-D) will be investigated and compared to Xyrem. The purpose of the study is to investigate how quickly and to what extent KEY-507 oral solutions are absorbed and eliminated from the body (this is called pharmacokinetics) when compared to Xyrem. This comparison is called the relative bioavailability. The safety of KEY-507 oral solutions and to what extent KEY 507 oral solutions are tolerated will also be investigated. In addition, you will be asked to evaluate the taste of the KEY-507 oral solutions and Xyrem.

Study design

Day 1 is the first day of administration of KEY-507 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 KEY-507 or Xyrem is separated by a period of 1 day. They will receive KEY 507 or Xyrem on Days 1, 3, 5, 7 and 9. During the study they will stay for 11 days (10 nights: from Day -1 to Day 10) in the clinical research center.

On the final study day (Day 10) they will undergo a post study screening, during which they will get similar examinations as in the pre-study screening (please refer to Chapter 10 of the information booklet). If the participation in the study is ended earlier than Day 10, they will be asked to undergo the post-study screening to make sure they are healthy when they leave the clinical research center.

The participation in the entire study, from pre-study screening until the post study screening, will be maximally 32 days.

Intervention

Treatment A: 1 x 9 mL KEY-507-A
Treatment B: 1 x 9 mL KEY-507-G
Treatment C: 1 x 9 mL KEY-507-C
Treatment D: 1 x 9 mL KEY-507-D
Treatment E: 1 x 9 mL Xyrem

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.

Contacts

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Jazz Pharmaceuticals, Inc.

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Scientific
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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 of age, inclusive
BMI 20 - 30 kg/m2, inclusive
minimum bodyweight 60 kg
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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	26-04-2016

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-05-2016
Application type:	First submission
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□001418□60-NL
CCMO	NL57517.056.16