# An open-label, randomized, crossover study to evaluate the pharmacokinetics, bioavailability, and bioequivalence following administration of JZP-507 oral solution and Xyrem®in healthy subjects.

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The purpose of the study is to investigate how quickly and to what extent JZP-507 is absorbed and eliminated from the body (this is called pharmacokinetics). This will be compared to the pharmacokinetics of Xyrem®. If the results show that the...

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Sleep disturbances (incl subtypes) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45490

**Source**
ToetsingOnline

**Brief title**
JZP-507 PK, BA and BE 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:** JZP-507, Narcolepsy, Xyrem

## Outcome measures

### Primary outcome

To confirm the bioequivalence of JZP-507 oral solution compared with Xyrem oral

solution under fasting conditions.

### Secondary outcome

To assess the food effect on pharmacokinetics of JZP-507.

To assess the safety and tolerability of JZP-507 oral solution and Xyrem.

# Study description

### Background summary

JZP-507 oral solution 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 (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]). Sodium oxybate/GHB is a substance that has depressant or sedating effects in people. Xyrem® is an oral solution that contains a high amount of sodium when given at the highest approved dose. JZP-507 contains the same active molecule or substance (oxybate) as Xyrem®, but contains less sodium to reduce the daily intake of sodium during treatment. JZP-507 is in development and is not registered as a drug but has been given to humans before.

### Study objective

The purpose of the study is to investigate how quickly and to what extent JZP-507 is absorbed and eliminated from the body (this is called pharmacokinetics). This will be compared to the pharmacokinetics of Xyrem®. If the results show that the pharmacokinetics of JZP-507 and Xyrem® are comparable, they will be considered *bioequivalent*. In addition, the effect of food on the pharmacokinetics of JZP-507 will be investigated. The safety and tolerability of JZP-507 and Xyrem® will also be carefully monitored during the study. In this study, each volunteer will receive JZP-507 as well as Xyrem® to be able to compare results within each volunteer. This study will be performed in up to 60 healthy male and female volunteers.

**Study design**

Day 1 is the first day of administration of study compound (JZP-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 administration of study compound is separated by a period of 1 day. The volunteers will receive JZP-507 or Xyrem® on Days 1, 3 and 5. During the study they will stay in the clinical research center for 7 days (6 nights: from Day -1 to Day 6). On the final study day (Day 6) they will undergo a post-study screening, during which they will be subjected to similar examinations as during the pre-study screening. I
f the participation in the study is ended earlier than Day 6 for any reason, they will be asked to undergo the post-study evaluations to check on their safety and to complete any final tests. They will leave the clinical research center on Day 6. The participation in the entire study, from the pre-study screening until the post-study screening, will be a maximum of 27 days.

**Intervention**

Treatment A: 9 milliliters JZP-507 (equivalent to 4.5 grams sodium oxybate), no food, once.
Treatment B: 9 milliliters JZP-507 (equivalent to 4.5 grams sodium oxybate), with food, once.
Treatment C: 9 milliliters Xyrem® (equivalent to 4.5 grams sodium oxybate), no food, once.

**Study burden and risks**

Pain, minor bleedings, bruises, possibly an infection.

# Contacts

**Public**
Jazz Pharmaceuticals

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US
**Scientific**
Jazz Pharmaceuticals

Porter Drive 3180
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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, inclusive
BMI 20 -30 kg/m2, inclusive
Weight minimum 60 kilogram
non smokers

## 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

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 60 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Xyrem® |
| Generic name: | n.a. |
| Registration: | Yes - NL intended use |

# Ethics review

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| Approved WMO Date: | 30-01-2017 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 21-02-2017 |

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|---|---|
| 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 | EUCTR2016-004709-14-NL |
| CCMO | NL60494.056.17 |