A randomized, double-blind, crossover taste testing study in healthy subjects comparing JZP-258 and placebo.

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The purpose of this study is to compare the taste of JZP-258 to placebo (a medicine without any active ingredient or fake medicine) for sameness. This is to ensure that when used in other studies, subjects will not taste a difference between both…

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

Summary

ID

NL-OMON46727

Source
ToetsingOnline

Brief title
JZP-258 Taste testing 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: JZP-258, Narcolepsy

Outcome measures

Primary outcome

De mogelijkheid om onderscheid te maken tussen JZP-258 en placebo voor beide

replicaten.

Secondary outcome

Not applicable.

Study description

Background summary

JZP-258 is a new compound that is being tested in other studies for the treatment of narcolepsy. Narcolepsy is defined as a rapid eye movement sleep disorder resulting for the dysregulation of the sleep-wake cycle. Symptoms include periods of excessive daytime sleepiness that may last from seconds to minutes and may occur at any time. Other symptoms are sudden loss of muscle strength, inability to move or hallucinations.

JZP-258 is a combination of 4 oxybate salts: sodium oxybate, potassium oxybate, calcium oxybate, and magnesium oxybate. A similar compound with sodium oxybate as the active compound (called Xyrem*) is already on the market for more than 10 years. Sodium oxybate is also known as the sodium salt of gamma-hydroxybutyric acid (GHB).

Sodium oxybate is a substance that has respiratory depressant (slowing breathing rate) or sedating effects in people. Xyrem® is an oral solution that contains a lot of sodium. When taking a maximum dose of 9 gram per night, the amount of sodium exceeds the allowable daily intake. By combining different oxybate salts, the amount of daily intake of sodium will be reduced.

Study objective

The purpose of this study is to compare the taste of JZP-258 to placebo (a medicine without any active ingredient or fake medicine) for sameness. This is to ensure that when used in other studies, subjects will not taste a difference

between both compounds.

Study design

The volunteers will stay in the research center in Groningen (UMCG) for 3 days (2 nights).

Day 1 is the day of taste testing of the study compound. The volunteers are expected at the research center at 14:00 h in the afternoon prior to the day of tasting the study compound (Day -1). They will leave the research center on Day 2 of the study.

JZP-258 and placebo will be prepared as an oral solution. The volunteers will be asked to taste the amount of 30 mL of the solution (pour liquid into your mouth, assess the taste, and spit it back to the vial). They only need to taste, they must not swallow the compound. The volunteers will have to taste 2 solutions 4 times (i.e. one pair of solutions each time) on one day (Day 1). Each time, they will be asked to compare one pair of solutions. There are 3 different pairs of solutions that will be compared, these are:
- Pair 1: JZP-258 and JZP-258
- Pair 2: JZP-258 and placebo
- Pair 3: placebo and JZP-258

They will receive Pair 1 2 times, Pair 2 once, and Pair 3 once. This means that overall, they will receive JZP-258 6 times and placebo 2 times.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises and possibly an infection.

Contacts

Public
Jazz Pharmaceuticals

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy male or female
18 - 50 years of age
(BMI) 18.0 - 35.0 kilograms/meter2
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:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2018
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-03-2018
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	EUCTR2017-004975-29-NL
CCMO	NL64848.056.18