A COMPARATIVE, OPEN-LABEL, RANDOMIZED, 2 PERIODS, 2 SEQUENCES CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY OF SODIUM OXYBATE FOR EXTENDED RELEASE ORAL SUSPENSION (FT218) FORMULATION (SINGLE DOSE ADMINISTERED AT THE DOSE OF 6 G) VERSUS THE MARKETED REFERENCE XYREM® (AT THE DOSE OF 2*3 G) IN HEALTHY VOLUNTEERS

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FT218 is a new formulation (composition) of the registered drug sodium oxybate. Sodium oxybate (also known as the sodium salt of gamma-hydroxybutyric acid [GHB]) is registered under the name Xyrem® for the treatment of narcolepsy. The purpose of...

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

Summary

ID

NL-OMON44321

Source
ToetsingOnline

Brief title
FT218 Bioavailability versus Xyrem®

Condition

- Sleep disturbances (incl subtypes)

Synonym
Cataplexy, Narcolepsy

Research involving
Human

Sponsors and support

Primary sponsor: Flamel Ireland Limited (Ltd) trading under the business name Avadel Ireland
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: FT218, Narcolepsy, Xyrem

Outcome measures

Primary outcome

To assess the pharmacokinetics (PK) and relative bioavailability of a single

dose of 6 g FT218 formulation taken 2 hours post-evening meal versus 2 doses of

3 g of Xyrem® administered 4 hours apart, first intake 2 hours post-evening

meal in healthy volunteers.

Secondary outcome

To assess the safety and tolerability of a single dose of 6 g FT218 formulation

taken 2 hours post-evening meal versus 2 doses of 3 g of the reference

treatment (Xyrem®) administered 4 hours apart, first intake 2 hours

post-evening meal, in healthy volunteers.

Study description

Background summary

FT218 is a new compound that may eventually be used for the treatment of narcolepsy. Narcolepsy is a sleeping disorder that involves excessive daytime sleepiness. For some people with narcolepsy it also involves a sudden loss of muscle tone (cataplexy), usually triggered by strong emotion. Sodium oxybate/GHB is a substance that has depressant or sedating effects in people. Xyrem® is an oral solution that has to be taken at bedtime, and then again 2.5 to 4 hours later. This dosing schedule is considered inconvenient for the patients because they have to wake up in the middle of the night to take the second dose. FT218 contains the same active molecule or substance (sodium oxybate) as Xyrem®, but in a special formulation which provides slower and longer release of the active substance. As a result, FT218 only has to be taken once at bedtime. FT218 is in development and is not registered as a drug, but it has been given to humans before.

FT218 is made of the active ingredient sodium oxybate encapsulated in very small particles made of naturally occurring substances (polymers). Flamel has conducted all research and studies needed to show that the particles used can be broken down by the human body and that the components are not harmful. These particles have been used previously in humans without any safety concern.

Study objective

FT218 is a new formulation (composition) of the registered drug sodium oxybate. Sodium oxybate (also known as the sodium salt of gamma-hydroxybutyric acid [GHB]) is registered under the name Xyrem® for the treatment of narcolepsy. The purpose of this study is to investigate how safe the new compound FT218 is when it is administered to healthy subjects in a single dose of 6 g.

It will also be investigated how quickly and to what extent FT218 is absorbed and eliminated from the body (this is called pharmacokinetics), this will be compared to 2 doses, 4 hours apart, of the reference product Xyrem® (2*3 g).

Study design

The study will be performed in 2 periods. During the study the volunteers will receive FT218 (6 g) in one period in the evening (around 22:00 h) of Day 1, 2 hours after completion of a standard dinner, as an oral drink (a suspension) of 50 milliliters (Treatment A). After administration of the study compound, the dosing cup will be rinsed once with 20 milliliters of water, which they will also be required to drink. They will receive Xyrem® in the other period (Treatment B). The first dose Xyrem® (3 g) will take place in the evening (around 22:00 h) of Day 1, 2 hours after completion of a standard dinner, as an oral drink (a suspension) of 60 milliliters. The volunteers will receive the second dose (3 g) 4 hours later.

One of the investigators will inspect the mouth after the study compound intake.

During the study they will receive standard meals and snacks at scheduled times. In-between meals and snacks only water is allowed and no other food or drinks. From 1 hour before until 1 hour after administration of the study compound they are not allowed to drink water (except for the water given with the study compound).

The order in which they will receive FT218 or Xyrem® will be determined by chance. A total of 14 volunteers will receive FT218 in Period 1 and Xyrem® in Period 2, and 14 other volunteers will receive Xyrem® in Period 1 and FT218 in Period 2.

Intervention

Not applicable

Study burden and risks

Pain, minor bleedings, bruises and possibly an infection.

Contacts

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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 (Caucasian)
age 18 - 55 years, including
(BMI) 18.0 - 28.0 kilograms/meter2
weight at least 60 kg
not 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2017
Enrollment:	28
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	17-10-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-10-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-11-2017
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	EUCTR2016-004342-28-NL
CCMO	NL63519.056.17