AN OPEN-LABEL, RANDOMIZED, SINGLE DOSE, TWO-TREATMENT (FED VS FASTING), TWO-PERIOD, TWO-SEQUENCE CROSSOVER STUDY TO ASSESS THE EFFECT OF FOOD ON SODIUM OXYBATE FOR EXTENDED RELEASE ORAL SUPENSION (FT218) FORMULATION ADMINISTRERED AT 6 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 (excessive...

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

Summary

ID

NL-OMON44554

Source
ToetsingOnline

Brief title
FT218 PK, FE Study in Healthy Subjects

Condition

- Sleep disturbances (incl subtypes)

Synonym
cataplexy and 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

Outcome measures

Primary outcome

To assess the pharmacokinetics (PK) and of a single dose of 6 g FT218 taken 30

minutes after the start of a standardized meal (fed condition) vs. 6 g FT218

taken after a 10-hour overnight fast (fasted condition) in healthy volunteers.

Secondary outcome

To assess the safety of a single dosing of 6 g FT218 in fasted and fed states

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). Avadel 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 (excessive sleepiness). FT218 has been given to humans before.

The purpose of this study is to investigate how food affects how quickly and to what extent FT218 is absorbed and eliminated from the body (this is called pharmacokinetics) when given in a single dose of 6 gram. It will also be investigated how safe the new compound FT218 is when it is administered to fasted and fed healthy subjects as a single dose of 6 grams.

Study design

The actual study will consist of 2 periods during which the volunteer will stay in the research center in Groningen Martini Hospital for 3 days (2 nights).

Day 1 is the first day of administration of the study compound. They are expected at the research center at 14:00 h in the morning prior to the day of first administration of the study compound (Day 1). They will leave the research center on Day 2 of the study.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

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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
age 18 - 55 years, inclusive
BMI 18.0 - 28.0 kilograms/meter2, inclusive
weight 60.0 kg or more.
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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2017
Enrollment:	16
Type:	Actual

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:	02-11-2017
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	EUCTR2016-004343-36-NL
CCMO	NL63517.056.17