An open label, sequential study to assess the drug-drug interaction of Divalproex Sodium extended release (ER) at steady-state on FT218 formulation administered at a single 6 g dose in healthy volunteeers

Published: 27-02-2018
Last updated: 12-04-2024

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...

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

Summary

ID

NL-OMON46476

Source
ToetsingOnline

Brief title
FT218 Divalproex Sodium Drug-Drug Interaction Study

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: divalproex, FT218

Outcome measures

Primary outcome

To assess the pharmacokinetics (PK) of a single 6 g dose of FT218 with or

without 1250 mg/day divalproex sodium ER at steady-state in healthy volunteers.

Secondary outcome

To assess the safety of a single dose of 6 g FT218 with or without 1250 mg/day

divalproex sodium ER at steady-state 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 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.

Divalproex sodium ER has been on the market as a drug for the treatment of epilepsy, mania / bipolar disorder and migraine. It is already known that the pharmacokinetics of Xyrem® is affected by divalproex sodium ER.

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 the influence of the compound divalproex sodium extended-release (ER) on the absorption, distribution, and elimination (this is called pharmacokinetics) of FT218 from the body, when it is administered to healthy participants. This study will indicate if divalproex sodium ER affects the concentrations of FT218 in the blood. FT218 has been administered to humans before. Divalproex sodium ER is not a new compound; the active component valproate is already available on the market in several dosages and formulations.

It will also be investigated whether FT218 given without and with divalproex sodium ER is safe.

Study design

The actual study will consist of 1 period during which the volunteers will stay in the research center in Groningen Martini Hospital for 14 days (13 nights).

Day 1 is the first day of administration of the study compound. The volunteers are expected at the research center at 14:00 h in the afternoon prior to the day of first administration of the study compound. They will leave the research center on Day 13 of the study.

During the study they will receive 6 gram (g) of FT218 as an oral drink (a suspension) of 50 milliliters (mL). After administration of the study compound, the dosing cup will be rinsed once with 20 mL of water, which will also be required to drink. During the study they will also receive 1250 milligram (mg) of divalproex sodium ER as oral tablets with 240 mL of water. One of the investigators will inspect the hands and mouth after the study compound intake.

FT218 and/or divalproex sodium ER is administered in the morning, 2 hours after

they have started a breakfast. After administration of the study compound(s), the volunteers will be required to fast for 4 additional hours on Day 1, Day 11 and Day 12. Then they will be served lunch. During fasting they are allowed to drink water, except during 1 hour before and 1 hour after administration of the study compound.

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 subjects
18-55 years, inclusive
BMI 18.0-28.0 kg/m2, inclusive
Weight >= 60 kg

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):	09-03-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2018
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-03-2018
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	EUCTR2017-005012-34-NL
CCMO	NL64760.056.18