One-sequence, two-period, open-label study to evaluate the effects of FTY720 on the pharmacokinetics of an oral contraceptive (levonorgestrel/ethinyl estradiol) in healthy female volunteers.

Published: 06-07-2009
Last updated: 06-05-2024

The purpose of this investigation is: • To examine how the new drug FTY720 (study medication) will be absorbed, metabolized and excreted by the body in combination with the contraception pill which consists of ethinyl-estradiol and levonorgestrel.•...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON35177

Source
ToetsingOnline

Brief title
FTY720D2114 OC interaction study

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerose

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma AG

Intervention

Keyword: females, interaction, OC

Outcome measures

Primary outcome

The main purpose of this investigation is to examine how the new drug FTY720 (study medication) will be absorbed, metabolized and excreted by the body in combination with the contraception pill which consists of ethinyl-estradiol and levonorgestrel.

Secondary outcome

The other purposes of this investigation are:

• To examine how the contraception pill, which consists of ethinyl-estradiol and levonorgestrel, will be absorbed, metabolized and excreted by the body in combination with the new drug FTY720 (study medication).

• To examine the safety and tolerability of the new drug FTY720 (study medication) in combination with the contraception pill which consists of ethinyl-estradiol and levonorgestrel.

Study description

Background summary

FTY720 is a new medication developed for the treatment of multiple sclerosis. Multiple sclerosis, mostly abbreviated as MS, is a disease of the central nervous system. Multiple sclerosis is caused by the immune system of the body.

In the beginning of the disease process the covering of the nerve bundles are degenerated in an irregular pattern. This cover, called myelin sheath, is the insulation around the nerves. Without this insulation the transmission of signals in the nerve is disrupted causing neurological disturbances in the patients like paralysis. MS is diagnosed often in adolescents and women are more often diagnosed than men. The cause of the disease is unknown but current theories are pointing on a combination of hereditary and environmental factors.

FTY720 acts on acertain type of white blood cells which are responsible for immunity. Therefore these cells will disappear at the place of the inflammation. This will decrease the degeneration process of the myelin sheath and the patient will experience less paralysis symptoms.

Study objective

The purpose of this investigation is:
• To examine how the new drug FTY720 (study medication) will be absorbed, metabolized and excreted by the body in combination with the contraception pill which consists of ethinyl-estradiol and levonorgestrel.
• To examine how the contraception pill, which consists of ethinyl-estradiol and levonorgestrel, will be absorbed, metabolized and excreted by the body in combination with the new drug FTY720 (study medication).
• To examine the safety and tolerability of the new drug FTY720 (study medication) in combination with the contraception pill which consists of ethinyl-estradiol and levonorgestrel.

Study design

One-sequence, two-period, open-label study to evaluate the effects of FTY720 on the pharmacokinetics of an oral contraceptive (levonorgestrel/ethinyl estradiol) in healthy female volunteers

Intervention

The study (including screening and final visit) is taking place in the Xendo clinical research centre in Groningen.

The study will start with a screening. A physical examination and different standard test (ECG, blood pressure) will be performed during the screening appointment. Blood and urine samples will be taken for laboratorium tests and an alchol breath test and drug screen will be performed.

During the confinement the medication will be administered to the subjects on different occasions. Blood samples will also be taken at several occasions. Adverse events will be registered. On almost daily basis ECGs and vitals will be judged.

At the end of the study a follow-up visit will take place.

Study burden and risks

FTY720 is not a registered drug. This drug has been given to volunteer before and was well tolerated. Side effects were mentioned which are probably due to the medication. These were short of breath, low pulse, low blood pressure, a decreased electrical conduction of the heart, an increase of liver enzyme values in the blood and diarrhea.

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

Female, 18-40 years of age, BMI 18-29 kg/m2, OC-user, healthy

Exclusion criteria

Clinical significant abnormalities during screening and baseline

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):	14-07-2009
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	10-07-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	07-08-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-08-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-09-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-05-2010
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	EUCTR2009-011536-34-NL
CCMO	NL28444.056.09