An open-label, multiple-dose, sequential, 2 treatment period study to evaluate the effect of QBW251 on the pharmacokinetics and pharmacodynamics of a monophasic oral contraceptive in pre-menopausal healthy female volunteers

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- To assess the effect of QBW251 on the pharmacokinetics of a monophasic combined oral contraceptive containing 30 µg ethinyl estradiol (EE) and 150 µg levonorgestrel (LVG).- To assess the effect of QBW251 on the pharmacodynamics of a monophasic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON40637

Source
ToetsingOnline

Brief title
CQBW251X22102 (CS0216)

Condition

- Skin and subcutaneous tissue disorders congenital
- Menstrual cycle and uterine bleeding disorders

Synonym

CF, mucoviscidosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Confirmatory, Open-label, PD, PK

Outcome measures

Primary outcome

Confirmatory

PK

PD

Secondary outcome

Not applicable

Study description

Background summary

To study the pharmacokinetic and pharmacodynamic effects of QBW251 on the oral contraceptive pill.

Study objective

- To assess the effect of QBW251 on the pharmacokinetics of a monophasic combined oral contraceptive containing 30 µg ethinyl estradiol (EE) and 150 µg levonorgestrel (LVG).

- To assess the effect of QBW251 on the pharmacodynamics of a monophasic combined oral contraceptive containing 30 µg ethinyl estradiol (EE) and 150 µg levonorgestrel (LVG) as determined by Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), estradiol, Progesterone

and Sex Hormone Binding Globulin (SHBG) concentrations and ovarian follicle size as represented by the Hoogland Score.
- To assess the safety, tolerability of QBW251 when administered orally.
- To assess the pharmacokinetics of QBW251 when administered orally.

Study design

This is a confirmatory, phase I, open-label, single sequence, two-treatment period study in premenopausal healthy female volunteers.

Intervention

The study will start with a screening visit. During the screening visit standard medical assessments including safety laboratory tests (blood draw, urine collection), an alcohol breath test, urine drug screen, a physical examination, ECG and a vital signs measurement will be performed. In addition standard aPTT test and Factor V Leiden Mutation test be performed.

After the subject passes all above mentioned tests, the subject will be enrolled in the synchronization phase if the subject is not taking a monophasic OC for at least 3 cycles. The synchronization phase consists at least 3 OC cycles.

During study the subject will enter the clinic. In P1, the subjects will receive 1 medication (an OC) daily from day 1 to day 21. In P2, the subjects will receive 1 medication (an OC) daily from day 1 to day 21 and twice daily the study medication (QBW251). The subject will be asked on a regular basis for possible side effects, blood will be drawn for safety, PK, and PD measurements and the vital signs/ECG will be checked during the 2 confinement periods and ambulant visits. During the pill-free periods, the subject will not return to the clinic.

Finally a follow-up examination will be performed. During this visit the subjects will be asked for possible side effects, blood will be drawn for safety and PD, the vital signs/ECG will be checked and a physical examination will be conducted.

Study burden and risks

The risk is small. The patients will be closely monitored. The patients will be regularly questioned for any side effects and safety tests are scheduled (ECG / Vital Signs). The patients will be asked to report, as soon as possible, any changes in physical and/or mental well being.

The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting or an infection at the blood sampling site may

occur.

Shaving may be required for proper placemant of ECG patches. This may cause irritation or bleeding of the skin. ECG patches may cause redness, itching, rash, or blisters on the skin and/or hair loss due to removal of ECG patches.

Contacts

Public
Novartis

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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 premenopausal female subjects age 18 to 50 years of age. Stable regimen of monophasic OC containing EE (30 µg)/LVG (150 µg) for at least three cycles prior to dosing in treatment period.;Any Subject not taking any OC or taking another brand of;monophasic OC (which does not contain 30 µg EE and 150 µg LVG);should be willing to take a monophasic OC containing 30 µg EE and;150 µg LVG for at least three cycles during synchronization until day

-7.;Negative pregnancy test results at screening and both baseline;visits.

Exclusion criteria

Use of other investigational drugs at the time of enrollment, or within 5 half-lives of enrollment, or within 30 days, whichever is longer; or longer if required by local regulations.;Women of child-bearing potential, defined as all women;physiologically capable of becoming pregnant, unless they are using contraception methods.;Women who are either heterozygous or homozygous for the Factor V Leiden mutation.

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):	21-05-2015
Enrollment:	47
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	QBW251
Generic name:	QBW251

Ethics review

Approved WMO

Date:	06-05-2014

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2014
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	EUCTR2013-004895-36-NL
CCMO	NL49077.056.14