A Single-Dose, Open-Label, Randomized, 2-Way Crossover Pivotal Study to Assess the Bioequivalence of NGM/EE Tablets Manufactured at 2 Different Facilities

Published: 15-05-2014
Last updated: 21-04-2024

- To establish the bioequivalence of the hormones norgestimate, norelgestromin, and ethinyl estradiol in NGM/EE Schaffhausen tablets compared with the same hormones in NGM/EE Manati tablets.- To assess the safety and tolerability of both…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON40931

Source
ToetsingOnline

Brief title
10131CON1001 (CS0220)

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
birth control pill, Combination oral contraceptives

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag

Source(s) of monetary or material Support: Janssen Research and Development

Intervention

Keyword: bioequivalence, cross-over, safety, tolerability

Outcome measures

Primary outcome

bioequivalence

safety

tolerability

Secondary outcome

Not applicable

Study description

Background summary

To study the bioequivalence of NGM/EE tablets at 2 different facilities

Study objective

- To establish the bioequivalence of the hormones norgestimate, norelgestromin, and ethinyl estradiol in NGM/EE Schaffhausen tablets compared with the same hormones in NGM/EE Manati tablets.
- To assess the safety and tolerability of both formulations.

Study design

This is a single-dose, open-label, randomized, 2-way crossover pivotal study to assess the bioequivalence of NGM/EE tablets manufactured at 2 different facilities

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, breast examination, gynecologic examination with pelvic ultrasound, ECG and a vital signs measurement will be performed. In addition a Pap test will be done.

After the subject passes all above mentioned tests,the subject will be enrolled in the study.

During study the subject will enter the clinic. In P1, the subjects will receive 1 medication (an OC) once on day 1. In P2, the subjects will receive the other medication (an OC) once on day 1. The subject will be asked on a regular basis for possible side effects, blood will be drawn for PK and the vital signs will be checked during the 2 confinement periods. Finally a follow-up examination will be performed. During this visit the subjects will be asked for possible side effects, blood and urine will be collected for safety, the vital signs 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 (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 ECGpatches. 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Be a woman 18 to 45 years of age, inclusive .
- Signed an informed consent document indicating they understand the purpose of and procedures required for the study and are willing to participate in the study.
- Willing to adhere to the prohibitions and restrictions specified in this protocol (Section 4.4, Prohibitions and Restrictions).
- Must be either: 1. surgically sterile or 2. of child-bearing potential and be practicing an effective non-hormonal method of birth control (e.g., copper intrauterine device, double-barrier method, male partner sterilization) before entry and throughout the study. Women, who are not heterosexually active at Screening, must agree to utilize a highly-effective non-hormonal method of birth control if they become heterosexually active during their participation in the study.
- If a woman of child-bearing potential, must have a negative serum β-human chorionic gonadotropin (hCG) pregnancy test at screening; and a negative urine pregnancy test on Day -1 of the each treatment period.
- Must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the study and for 3 months after the last dose.
- Body mass index (BMI; weight [kg]/height2 [m]2) between 18.5 and 30 kg/m2 (inclusive), and body weight not less than 50 kg or higher than 90 kg (198 pounds).
- Blood pressure (after the subject is sitting for 5 minutes) between 90 and 140 mmHg systolic, inclusive, and no higher than 90 mmHg diastolic.
- A 12-lead ECG consistent with normal cardiac conduction and function.
- Non-smoker.

Exclusion criteria

- History of or current clinically significant medical illness including (but not limited to) cardiac arrhythmias or other cardiac disease, hematologic disease, coagulation disorders, lipid abnormalities, significant pulmonary disease, including bronchospastic respiratory disease, diabetes mellitus, hepatic impairment, renal insufficiency, thyroid disease, neurologic or psychiatric disease, infection, or any other illness that the investigator considers should exclude the subject or that could interfere with the interpretation of the study results.
- Contraindications to combined hormonal contraceptives.
- Clinically significant abnormal values for hematology, clinical chemistry or urinalysis at screening as deemed appropriate by the investigator
- Hematocrit less than 36%
- Clinically significant abnormal physical examination, vital signs or 12 lead ECG at screening or at admission to the study center as deemed appropriate by the investigator
- Abnormal Papanicolaou (Pap) smear or CytoRich test
- Use of any prescription or nonprescription medication (including vitamins and herbal supplements), except for paracetamol, within 14 days before the first dose of the study drug is scheduled
- Has a levonorgestrel implant (e.g., Norplant®) in place or removed within the 60 days before admission to the study site,
- Received medroxyprogesterone injection (e.g., Depo Provera®) within 6 months of admission to the study
- Use of any other hormonal contraceptive within 60 days of Day -1 of Period 1
- History of drug or alcohol abuse according to Diagnostic and Statistical Manual of Mental Disorders (4th edition) (DSM-IV) criteria within 2 years before Screening or positive test result(s) for alcohol and/or drugs of abuse (such as barbiturates, opiates, cocaine, cannabinoids, amphetamines and benzodiazepines) at Screening and Day -1 of the each treatment period
- Known allergy to the study drug or any of the excipients of the formulation
- Donated blood or blood products or had substantial loss of blood (more than 500 mL) within 3 months before the first administration of study drug or intention to donate blood or blood products during the study
- Received an experimental drug or used an experimental medical device within 1 month or within a period less than 10 times the drug*s half-life, whichever is longer, before the first dose of the study drug is scheduled
- Unable to swallow solid, oral dosage forms whole with the aid of water (participants may not chew, divide, dissolve, or crush the study drug)
- Pregnant, breast-feeding or planning to become pregnant during the study
- Positive test for human immunodeficiency virus (HIV) 1 and 2 antibodies, hepatitis B surface antigen (HBsAg), or hepatitis C antibodies
- History of smoking or use of nicotine-containing substances within the previous 2 months, as determined by medical history or subject*s verbal report, or positive urine cotinine test at screening and on Day -1 of the each treatment period
- Preplanned surgery or procedures that would interfere with the conduct of the study
- Employee of the investigator or study center, with direct involvement in the proposed study

or other studies under the direction of that investigator or study center, as well as family members of the employees or the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2014
Enrollment:	102
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cilest
Generic name:	norgestimate/ethinyl estradiol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	ORTHO CYCLEN
Generic name:	norgestimate/ethinyl estradiol

Ethics review

Approved WMO

Date:	15-05-2014

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-06-2014
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	EUCTR2014-000983-16-NL
CCMO	NL49100.056.14