A phase I, mono-center, randomized, placebo and comparator controlled, single blind, rising dose, clinical study to determine single dose pharmacokinetics, pharmacodynamics, safety and tolerability of four doses of FSH-GEX* according to adaptive design (25, 75, 150 and 300 IU) administered subcutaneously in healthy pituitary-suppressed female volunteers

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- To assess the safety and (local) tolerability of test compound following single rising dose administration by subcutaneous injection- To determine FSH pharmacokinetic parameters including Cmax and AUC0-last of test compound following single rising...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON36196

Source
ToetsingOnline

Brief title
GEXGP24101

Condition

- Sexual function and fertility disorders

Synonym
Infertility

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Placebo and comparator controlled, Rising dose, Safety and tolerability, Single blind

Outcome measures

Primary outcome

- To assess the safety and (local) tolerability of test compound following

single rising dose administration by subcutaneous injection

- To determine FSH pharmacokinetic parameters including Cmax and AUC0-last of

test compound following single rising dose administration

by subcutaneous injection.

Secondary outcome

- To assess the pharmacodynamic effect of test compound following single

rising dose administration by subcutaneous injection as

determined by Estradiol (E2) and inhibin B concentrations and ovarian

follicle size, as determined by transvaginal ultrasonography (TVUS)

Study description

Background summary

The aim of the current study is the pharmacokinetic and pharmacodynamic characterization of a single dose administration of four doses of test compound in healthy pituitary-suppressed female volunteers, in comparison with two marketed comparator products

Study objective

- To assess the safety and (local) tolerability of test compound following single rising dose administration by subcutaneous injection
- To determine FSH pharmacokinetic parameters including Cmax and AUC0-last of test compound following single rising dose administration by subcutaneous injection.
- To assess the pharmacodynamic effect of test compound following single rising dose administration by subcutaneous injection as determined by Estradiol (E2) and inhibin B concentrations and ovarian follicle size, as determined by transvaginal ultrasonography (TVUS)

Study design

This is a phase I, single blind, placebo and comparator controlled, randomized, single dose study in healthy adult female volunteers at 4 different dose levels. There will be one cohort of 18 subjects. This cohort has a three-period design and each volunteer will receive 3 successive dose levels during period 1-3

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 gynecological test will be performed including a cervical smear and TVUS assessment.

After the subject passes all above mentioned tests, the subject will be enrolled in the synchronization phase. On day -3 till day -1 there will be a pill-free interval. On day 1 till day 60 the subject will be pituitary suppressed using Marvelon®.

During study the subjects will enter the clinic, will receive 3 medication formulations, will be asked on a regular basis for possible side effects, blood

will be drawn for safety and PK measurements and the vital signs will be checked regularly during the 3 confinement periods. During the outpatient periods, the subject will return in regular intervals. During these visits the subjects will be asked for possible side effects, blood will be drawn for safety and PK measurements, the vital signs will be checked and the follicle sizes will be measured using TVUS regularly.

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, the vital signs/ECG will be checked and a physical examination will be conducted.

Study burden and risks

FSH-GEXTM has not been tested in humans. The side effects of the active ingredient of FSH-GEXTM is expected to be the same as the side effects reported for the comparator Gonal-F® and Bravelle®.

The most common side effects reported for both Gonal-f® and Bravelle® are: ovarian cysts, headache and local reaction at the injection site (pain, redness, bruising, swelling and/or irritation). Following multiple-dose treatment with Gonal-f® a condition called OHSS (Ovarian Hyper Stimulation Syndrome) can occur. The occurrence of this syndrome during this study is unlikely, because only single doses and no other drugs are given in this study. The syndrome is characterized by large ovarian cysts. First symptoms are pain in the lower abdominal region, possibly in combination with nausea, vomiting and weight gain. In rare cases of OHSS, serious complications may occur.

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 female subjects

Exclusion criteria

Clinical significant abnormalities at screening

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	08-04-2011
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bravelle®
Generic name:	Urofollitropin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Gonal-F®
Generic name:	Follitropin alfa
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Marvelon®
Generic name:	Ethinylestradiol / Desogestrel
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Microgynon 30®
Generic name:	Ethinylestradiol / Levonorgestrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-04-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-04-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	26-05-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-06-2011
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	EUCTR2011-001194-26-NL
CCMO	NL36217.056.11