A phase I, mono-center, placebo and comparator controlled, single-blind, randomized, parallel group, clinical study to determine multiple dose safety, tolerability, pharmacokinetics, and pharmacodynamics of FSH-GEX* administered subcutaneously in healthy pituitary-suppressed female volunteers

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- To assess the safety and tolerability of FSH-GEX* following multiple dose administration by subcutaneous injection- To determine the pharmacokinetic profile of FSH-GEX* following multiple dose administration by subcutaneous injection- To assess...

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

Summary

ID

NL-OMON35651

Source
ToetsingOnline

Brief title
GEXGP24102

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: Multiple dose, Placebo and comparator controlled, Safety and tolerability, Single blind

Outcome measures

Primary outcome

- To assess the safety and tolerability of FSH-GEX* following multiple dose

administration by subcutaneous injection

Secondary outcome

- To determine the pharmacokinetic profile of FSH-GEX* following multiple dose

administration by subcutaneous injection

- To assess the pharmacodynamic effect of FSH-GEX* following multiple dose

administration by subcutaneous injection as determined by Luteinizing Hormone

(LH), 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 to investigate the safety and (local)
tolerability of FSH-GEX* following multiple dose administration by

subcutaneous injection in healthy pituitary-suppressed female volunteers, in comparison with two marketed products

Study objective

- To assess the safety and tolerability of FSH-GEX* following multiple dose administration by subcutaneous injection
- To determine the pharmacokinetic profile of FSH-GEX* following multiple dose administration by subcutaneous injection
- To assess the pharmacodynamic effect of FSH-GEX* following multiple dose administration by subcutaneous injection as determined by Luteinizing Hormone (LH), 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, multiple dose study in healthy adult female volunteers at 3 different dose levels. There will be five cohorts: cohorts 1,2,3 and 5 consists of 12 subjects and cohort 4 consists of 8 subjects. In cohort 1, 10 subjects will receive FSH-GEX* and 2 subjects will receive placebo. In cohort 2, 12 subjects will receive either 150 IU Gonal-f® or 150 IU Bravelle®. In cohort 3, 10 subjects will receive FSH-GEX* and 2 subjects will receive placebo. In cohort 4, 8 subjects will receive will receive either 150 IU Gonal-f® or 150 IU Bravelle®. In cohort 5, 10 subjects will receive FSH-GEX* and 2 subjects will receive placebo. Each subject will receive maximally 7 daily doses of FSH-GEX* or Gonal-f® or Bravelle® or placebo.

Intervention

n.a.

Study burden and risks

The side effects of the active ingredient of FSH-GEX* 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 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

Clinically 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):	13-10-2011
Enrollment:	95
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

Ethics review

Approved WMO

Date:	07-10-2011
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-10-2011
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	EUCTR2011-004600-38-NL
CCMO	NL38268.056.11