ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 01/10/2014

ClinicalTrials.gov ID: NCT01297465

Study Identification

Unique Protocol ID:	EMR 200061-504
Brief Title:	PERgoveriS In Stratified Treatment for Assisted Reproductive Technique (PERSIST)
Official Title:	A Phase IIIB, Multicentre, Multinational, Randomized, Open-label Trial to Compare the Efficacy and Safety of Ovarian Stimulation With GONAL-f® Day 1 to Day 5 Followed by Pergoveris® Starting Day 6 to Pergoveris® Starting Day 1 in Women Between 36 and 40 Years of Age Undergoing Assisted Reproductive Technique (ART)
Secondary IDs:	2010-023534-23 [EudraCT Number]

Study Status

Record Verification:	January 2014
Overall Status:	Completed
Study Start:	May 2011
Primary Completion:	October 2012 [Actual]
Study Completion:	October 2012 [Actual]

Sponsor/Collaborators

Sponsor:	Merck KGaA
Responsible Party:	Sponsor
Collaborators:	Merck Serono S.A., Geneva Merck A/S, Denmark Merck OY, Finland Merck Serono S.A.S, France Merck Serono GmbH, Germany Merck A.E., Greece

Merck B.V., Netherlands
Merck SP. Z.O.O., Poland
Merck Serono S.P.A., Italy
Merck Services U.K. Ltd, UK
LLC Merck, Russia
Merck spol. s r.o., Slovakia
Merck Pharma, K.S., Slovakia

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved
Approval Number: 05/16/2011
Board Name: Geschäftsstelle der Ethik-Kommission der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg
Board Affiliation: Martin-Luther-Universität Halle-Wittenberg
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Data Monitoring?:

Plan to Share Data?:

Oversight Authorities: Denmark: Danish Medicines Agency
Finland: Finnish Medicines Agency
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
Germany: Federal Institute for Drugs and Medical Devices
Greece: National Organization of Medicines
Italy: The Italian Medicines Agency
Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Slovakia: State Institute for Drug Control
United Kingdom: Medicines and Healthcare Products Regulatory Agency
Russia: Ministry of Health of the Russian Federation

Study Description

Brief Summary: This is a multicenter, multi-national, randomized, open-label comparative trial. After screening, the subjects will start down-regulation treatment on Day 21-22 of the cycle. Down-regulation treatment will start within 2 months following the screening visit. The routine long luteal phase protocol for gonadotropin-releasing hormone (GnRH) agonist treatment will be followed. Once down-regulation has been confirmed, a pregnancy test will be performed just before randomization and start of recombinant human follicle-stimulating hormone (r-hFSH) treatment to rule out any pre-existing pregnancy. If the result is negative, the subject will be randomly assigned to one of the two treatment arms of the trial:

- GONAL-f®: (Liquid Pen; 300 international unit [IU] of per day) stimulation Day 1-5 followed by Pergoveris® (vial/powder, 300 IU per day) from stimulation Day 6 and until required recombinant human chorionic hormone (r-hCG) criterion is met. The dose can be adjusted from stimulation Day 6 (increased or decreased) based upon the subject's ovarian response and according to the center's standard practice.
- Pergoveris®: (vial/powder, 300 IU per day) from stimulation Day 1 and until required r-hCG criterion is met. The dose can be adjusted from stimulation Day 6 (increased or decreased) based upon the subject's ovarian response and according to the center's standard practice.

Randomization across the two treatment arms will be kept balanced in a 1:1 ratio. Follicular development will be monitored according to the center's standard practice by ultrasound (US) and/or estradiol (E2) levels, until the protocol r-hCG requirement is met (i.e., at least one follicle greater than or equal to [>=] 18 millimeter [mm] and two follicles >=16 mm). After this, a single injection of r-hCG will be administered in order to induce final oocyte maturation.

At a time of 34-38 hours after r-hCG administration, oocytes will be recovered vaginally under US monitoring. Oocytes will then be fertilized in vitro and embryos replaced 2-5 days after oocyte recovery. Ovum pick up (OPU), in vitro fertilization (IVF), embryo transfer (ET) and luteal support will be performed as per center's standard practice.

A post-treatment safety visit will be performed for all subjects who received r-hCG (pregnant and non- pregnant) on Day 15-20 post-hCG. For subjects who have withdrawn from treatment (i.e. after starting Pergoveris® or Gonal-f® but before hCG is given) this visit will take place 20-30 days after their first Pergoveris® or Gonal-f® treatment injection (excluding pregnancy testing).

Detailed Description:

Conditions

Conditions: Assisted Reproductive Techniques
Reproductive Technology, Assisted

Keywords: Ovulation Induction
Ovarian Stimulation
Reproductive Technique, Assisted
Assisted Reproductive Technics
Assisted Reproductive Technique
Reproductive Technology, Assisted

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	202 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Gonal-f® Plus Pergoveris®	Drug: Gonal-f® Gonal-f® (follitropin alfa) 300 International Unit (IU) will be administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5). Other Names: • Follitropin alfa Drug: Pergoveris® Pergoveris® (follitropin alfa and lutropin alfa) 300 IU will be administered subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) administration day (at least 1 follicles >= 18 mm). The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice. Drug: Recombinant human chorionic gonadotropin (r-hCG) 250 microgram of r-hCG will be administered once subcutaneously on r-hCG day (at least 1 follicles >= 18 mm). Other Names: • Ovidrel® • Ovitrelle®
Experimental: Pergoveris®	Drug: Pergoveris® Pergoveris® (follitropin alfa and lutropin alfa) 300 IU will be administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice. Drug: Recombinant human chorionic gonadotropin (r-hCG) 250 microgram of r-hCG will be administered once subcutaneously on r-hCG day (at least 1 follicles >= 18 mm). Other Names: • Ovidrel® • Ovitrelle®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 36 Years

Maximum Age: 40 Years

Gender: Female

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Be a female subject justifying an in vitro fertilization and embryo transfer (IVF/ET) treatment
- Be between her 36th and 40th birthday (both included) at the time of the randomization visit
- Have early follicular phase (Day 2-4) serum level of basal follicle stimulating hormone (FSH less than or equal to (=<)12 IU/L) measured in the center's local laboratory during the screening period (that is within 2 months prior to down-regulation start)
- A body mass index (BMI) less than (<) 30 kilogram per square meter (kg/m^2)
- Have a regular spontaneous ovulatory menstrual cycle between 21 and 35 days in length
- Be willing and able to comply with the protocol for the duration of the trial
- Have given written informed consent, prior to any trial-related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the subject at any time without prejudice to her future medical care
- Have a male partner with semen analysis within the past 6 months prior to randomization considered adequate to proceed with regular insemination or intracytoplasmic sperm injection (ICSI) according to the center's standard practice. If these criteria are not met, the subject can only be entered if donor sperm will be used
- Other protocol specified inclusion criteria could also apply.

Exclusion Criteria:

- Had >= 2 previous ART cycles with a poor response to gonadotrophin stimulation defined as =< 6 mature follicles and/or =<4 oocytes collected in any previous IVF cycle or previous cycles with a hyper response defined as >= 25 oocytes retrieved
- Any medical condition, which in the judgment of the investigator may interfere with the absorption, distribution, metabolism or excretion of the drug. In case of doubt, the subject in question should be discussed with Merck Serono's medical responsible
- Had previous severe ovarian Hyperstimulation Syndrome (OHSS)
- Polycystic ovary syndrome (PCOS; Rotterdam criteria) to reduce the risk of the occurrence of OHSS
- Any contraindication to being pregnant and/or carrying a pregnancy to term
- History of 3 or more miscarriages (early or late miscarriages) due to any cause
- A clinically significant systemic disease
- Known infection with Human Immunodeficiency Virus (HIV), Hepatitis B or C virus in the trial subject or her male partner
- Known allergy or hypersensitivity to human gonadotrophin preparations
- Entered previously into this trial or simultaneous participation in another clinical trial.

- Pregnancy and lactation period
- Participation in another clinical trial within the past 30 days
- Other protocol specified inclusion criteria could also apply.

Contacts/Locations

Study Officials: Salvatore Longobardi, MD
Study Director
Merck Serono S.p.A., an affiliate of Merck KGaA, Darmstadt, Germany

Locations: Germany
Merck Serono Research Site
Halle, Germany

Greece
Merck Serono Research Site
Athen, Greece

Merck Serono Research Site
Heraklion, Crete, Greece

Merck Serono Research Site
Pylaia, Thessaloniki, Greece

Finland
Merck Serono Research Site
Helsinki, Finland

Italy
Merck Serono Research Site
Torino, Italy

Merck Serono Research Site
Firenze, Italy

Merck Serono Research Site
Bologna, Italy

Germany
Merck Serono Research Site
Berlin, Germany

Denmark
Merck Serono Research Site

Dronninglund, Denmark

Merck Serono Research Site
Fredericia, Denmark

Netherlands
Merck Serono Research Site
Zwolle, Netherlands

Slovakia
Merck Serono Research Site
Bratislava, Slovakia

Poland
Merck Serono Research Site
Warszawa, Poland

Russian Federation
Merck Serono Research Site
Samara, Russian Federation

Merck Serono Research Site
Moscow, Russian Federation

United Kingdom
Merck Serono Research Site
London, United Kingdom

Merck Serono Research Site
Swansea, United Kingdom

France
Merck Serono Research Site
Clamart CEDEX, France

Merck Serono Research Site
Bondy CEDEX, France

Merck Serono Research Site
Tenon, France

Merck Serono Research Site
Bruges, France

Merck Serono Research Site
Villeurbanne, France

References

Citations: [Study Results] H Behre, C Howles, S Longobardi. Luteinizing hormone supplementation from Day 1 versus 6 of ovarian stimulation in women aged 36-40 years: results from an open-label, randomized, multicentre, multinational trial. Human Reproduction. 2013;28(suppl 1)

Links: URL: http://eshre13.m.tap.cr/webview/metadata/18117/30587
Description Related Info

URL: http://humrep.oxfordjournals.org/content/28/suppl_1.toc
Description Related Info

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Overall Study

	Gonal-f® Plus Pergoveris®	Pergoveris®
Started	99	103
Completed	91	93
Not Completed	8	10

	Gonal-f® Plus Pergoveris®	Pergoveris®
Lack of Ovarian Response	1	1
Ovarian hyperstimulation syndrome risk	0	1
No Oocytes Retrieved	1	1
Poor oocyte quality	0	1
No Fertilization	6	4
All Embryos Discarded	0	1
Intention to Freeze all Embryos	0	1

Baseline Characteristics

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Baseline Measures

	Gonal-f® Plus Pergoveris®	Pergoveris®	Total
Number of Participants	99	103	202
Age, Continuous [units: years] Mean (Standard Deviation)	37.6 (1.16)	37.4 (1.14)	37.5 (1.15)

	Gonal-f® Plus Pergoveris®	Pergoveris®	Total
Gender, Male/Female [units: participants]			
Female	99	103	202
Male	0	0	0
Race [units: participants]			
Black	4	3	7
Asian	4	6	10
Other	2	2	4
White	89	92	181
Height [units: centimeter] Mean (Standard Deviation)	166.1 (6.49)	166.3 (6.47)	166.2 (6.46)
Weight [units: kilogram] Mean (Standard Deviation)	64.81 (10.364)	65.82 (8.923)	65.33 (9.645)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Total Number of Oocytes Retrieved
Measure Description	The total number of oocytes retrieved per reporting group on the day of ovum pick-up (OPU) (34-38 hours post r-hCG day) was calculated. Oocyte retrieval is a technique used in in-vitro fertilization (IVF) in order to remove oocytes from the ovary of the female participant, enabling fertilization outside the body.
Time Frame	OPU day (34-38 hours post r-hCG day [end of stimulation cycle {approximately 11 days}])
Safety Issue?	No

Analysis Population Description

Modified intention-to-treat (Mod-ITT) population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and completed the primary efficacy assessment.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	98	101
Total Number of Oocytes Retrieved [units: oocytes] Mean (Standard Deviation)	10.9 (6.5)	9.7 (6.9)

Statistical Analysis 1 for Total Number of Oocytes Retrieved

Statistical Analysis Overview	Comparison Groups	Gonal-f® Plus Pergoveris®, Pergoveris®
	Comments	The null hypothesis was that the difference between the mean number of oocytes is less than (-3) or greater than (+3) between the two treatment arm. The alternate hypothesis was that the difference is between (-3) and (+3). The study had 80% power to show that the group randomized to Pergoveris® has an absolute difference of no more than 3 oocytes retrieved in comparison to the group randomized to GONAL-f®/Pergoveris®
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANOVA
	Comments	ANOVA model adjusted for treatment and country

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.28
	Confidence Interval	(2-Sided) 95% -3.15 to 0.59
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.947
	Estimation Comments	The primary efficacy variable was to be analyzed using an analysis of variance (ANOVA) model, adjusted for treatment and country.

2. Secondary Outcome Measure:

Measure Title	Total Dose and Mean Daily Dose of Follicle Stimulating Hormone (FSH)
Measure Description	
Time Frame	Day 1 up to r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	No

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	99	103

	Gonal-f® Plus Pergoveris®	Pergoveris®
Total Dose and Mean Daily Dose of Follicle Stimulating Hormone (FSH) [units: IU] Mean (Standard Deviation)		
Total Dose	3292 (851)	3321 (850)
Mean Daily Dose	307 (43)	311 (41)

3. Secondary Outcome Measure:

Measure Title	Total Number of Stimulation Treatment Days
Measure Description	
Time Frame	Day 1 up to r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	No

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	99	103
Total Number of Stimulation Treatment Days	10.6 (1.6)	10.6 (1.7)

	Gonal-f® Plus Pergoveris®	Pergoveris®
[units: days] Mean (Standard Deviation)		

4. Secondary Outcome Measure:

Measure Title	Implantation Rate
Measure Description	Implantation rate per reporting group was measured as the number of fetal sacs observed, divided by the number of embryos transferred multiplied by 100.
Time Frame	Days 35-42 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	No

Analysis Population Description

Mod-ITT population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and completed the primary efficacy assessment.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	90	93
Implantation Rate [units: percent sacs per embryo] Mean (Standard Deviation)	13.3 (29.1)	24.7 (36.1)

5. Secondary Outcome Measure:

Measure Title	Number of Fetal Sacs With Activity
Measure Description	Number of fetal sacs with activity was evaluated by ultrasound scan
Time Frame	Days 35-42 post r-hCG day [end of stimulation cycle {approximately 11 days}])
Safety Issue?	No

Analysis Population Description

Mod-ITT population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and completed the primary efficacy assessment."N" (number of participants analyzed) signifies those participants who were evaluable for this outcome measure.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	18	35
Number of Fetal Sacs With Activity [units: fetal sacs] Mean (Standard Deviation)	1.4 (0.5)	1.2 (0.4)

6. Secondary Outcome Measure:

Measure Title	Number of Fetal Hearts With Activity

Measure Description	Number of fetal hearts with activity was evaluated by ultrasound scan
Time Frame	Days 35-42 post r-hCG day [end of stimulation cycle {approximately 11 days}])
Safety Issue?	No

Analysis Population Description

Mod-ITT population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and completed the primary efficacy assessment."N" (number of participants analyzed) signifies those participants who were evaluable for this outcome measure.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	17	32
Number of Fetal Hearts With Activity [units: fetal hearts] Mean (Standard Deviation)	1.4 (0.5)	1.3 (0.5)

7. Secondary Outcome Measure:

Measure Title	Clinical Pregnancy Rate
Measure Description	Clinical pregnancy was defined as pregnancy diagnosed by ultrasonographic visualization of one or more gestational sacs or definitive clinical signs of pregnancy. It includes ectopic pregnancy. Clinical pregnancy rate was reported as total clinical pregnancy rate, clinical pregnancy rate per cycle started and per embryo transfer [ET]).
Time Frame	Days 35-42 post r-hCG day (end of stimulation cycle [approximately 11 days])

Safety Issue?	No

Analysis Population Description

Mod-ITT population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and had completed the primary efficacy assessment. "N" signifies those participants who had their ET in study treatment cycle. "n" signifies those participants who were evaluated for this measure in specified categories.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	97	101
Clinical Pregnancy Rate [units: percentage of participants]		
Total clinical pregnancy rate (n=97, 101)	17.5	31.7
Clinical pregnancy rate per cycle (n=97, 101)	17.5	31.7
Clinical pregnancy rate per ET (n=90, 93)	18.9	34.4

8. Secondary Outcome Measure:

Measure Title	Number of Participants With Cancelled Cycles Due to Excessive or Insufficient Ovarian Response to Treatment
Measure Description	An excessive ovarian response: greater than or equal to 25 oocytes which could put the participant at risk of OHSS; An insufficient ovarian response: defined as 3 or less follicles of greater than or equal to 12 millimeter developing following at least 7 days of treatment.

Time Frame	S1 until Day 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	No

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	99	103
Number of Participants With Cancelled Cycles Due to Excessive or Insufficient Ovarian Response to Treatment [units: participants]		
Insufficient ovarian response	1	1
Excessive ovarian response	0	1

9. Secondary Outcome Measure:

Measure Title	Biochemical Pregnancies Rate
Measure Description	Biochemical pregnancy was defined as the pregnancy diagnosed only by the detection of human chorionic gonadotropin (hCG) in serum or urine and that does not develop into a clinical pregnancy. Participants with beta- hCG concentration greater than 10 international units per liter (IU/L) were considered as biochemical pregnant.

Time Frame	Days 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	No

Analysis Population Description

Mod-ITT population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and completed the primary efficacy assessment. . "N" (number of participants analyzed) signifies those participants who had their embryo transfer in study treatment cycle.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	97	101
Biochemical Pregnancies Rate [units: participants]	23	41

10. Secondary Outcome Measure:

Measure Title	Number of Participants With Multiple Pregnancies
Measure Description	Multiple pregnancy was defined as the existence of more than one fetal sac with fetal heart activity.
Time Frame	Days 35-42 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	No

Analysis Population Description

Mod-ITT population included all the randomized participants who had received at least one dose of GONAL-f® or Pergoveris®, and completed the primary efficacy assessment. "N" (number of participants analyzed) signifies those participants who had their embryo transfer in study treatment cycle.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	97	101
Number of Participants With Multiple Pregnancies [units: participants]	6	8

11. Secondary Outcome Measure:

Measure Title	Number of Participants With Early and Late Ovarian Hyper Stimulation Syndrome (OHSS)
Measure Description	Ovarian Hyper Stimulation Syndrome (OHSS) is a syndrome which can manifest with enlarged ovaries, advanced ascites with increased vascular permeability, pleural fluid accumulation, hemoconcentration, and increased blood clotting. Early OHSS was defined as the onset of OHSS occurring within 9 days after oocyte retrieval and late OHSS was defined as the onset of OHSS occurring on or after day 10 from oocyte retrieval.
Time Frame	Days 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	Yes

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	99	103
Number of Participants With Early and Late Ovarian Hyper Stimulation Syndrome (OHSS) [units: participants]		
Early Ovarian hyperstimulation syndrome	4	1
Late Ovarian hyperstimulation syndrome	0	1

12. Secondary Outcome Measure:

Measure Title	Number of Participants With Treatment-emergent Adverse Events
Measure Description	An adverse event (AE) was defined as any untoward medical occurrence in the form of signs, symptoms, abnormal laboratory findings, or diseases that emerges or worsens relative to baseline during a clinical study with an Investigational Medicinal Product (IMP), regardless of causal relationship and even if no IMP has been administered.
Time Frame	Day 1 up to days 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	Yes

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	99	103
Number of Participants With Treatment-emergent Adverse Events [units: participants]	26	23

13. Secondary Outcome Measure:

Measure Title	Systolic and Diastolic Arterial Blood Pressure Assessments
Measure Description	
Time Frame	Days 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	Yes

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®. ."N" (number of participants analyzed) signifies those participants who were evaluable for this outcome measure.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	93	99
Systolic and Diastolic Arterial Blood Pressure Assessments [units: millimeter of mercury (mm Hg)] Mean (Standard Deviation)		
Systolic Blood Pressure	118.9 (12.8)	121.2 (14.8)
Diastolic Blood Pressure	74.8 (9.8)	76.8 (9.5)

14. Secondary Outcome Measure:

Measure Title	Heart Rate Assessments
Measure Description	
Time Frame	Days 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Safety Issue?	Yes

Analysis Population Description

Safety Population included all the randomized participants who had received at least 1 dose of Pergoveris® or Gonal-f®. ."N" (number of participants analyzed) signifies those participants who were evaluable for this outcome measure.

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Measured Values

	Gonal-f® Plus Pergoveris®	Pergoveris®
Number of Participants Analyzed	93	99
Heart Rate Assessments [units: beats per minute (bpm)] Mean (Standard Deviation)	75.7 (10.5)	76.5 (10)

Reported Adverse Events

Time Frame	Days 15-20 post r-hCG day (end of stimulation cycle [approximately 11 days])
Additional Description	[Not specified]

Reporting Groups

	Description
Gonal-f® Plus Pergoveris®	Gonal-f® (follitropin alfa) 300 International Unit (IU) was administered subcutaneously once daily from stimulation day 1 (S1) to stimulation day 5 (S5) followed by subsequent daily administration of Pergoveris® (follitropin alfa and lutropin alfa) 300 IU subcutaneously starting from S6 until recombinant human chorionic gonadotropin (r-hCG) (Ovidrel®/Ovitrelle®) administration day (at least 1 follicles greater than or equal to (>=) 18 millimeter [mm]). On r-hCG day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted based upon the participant's ovarian response and according to the site's standard practice.

	Description
Pergoveris®	Pergoveris® (follitropin alfa and lutropin alfa) 300 IU was administered subcutaneously once daily from S1 until r-hCG administration day (at least 1 follicles >= 18 mm). On r-hCG (Ovidrel®/Ovitrelle®) day, 250 microgram of r-hCG was administered once subcutaneously. The dose of Pergoveris® was adjusted starting from S6 based upon the participant's ovarian response and according to the site's standard practice.

Serious Adverse Events

	Gonal-f® Plus Pergoveris®	Pergoveris®
	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/99 (2.02%)	0/103 (0%)
Reproductive system and breast disorders		
Ovarian hyperstimulation syndrome [A] *	2/99 (2.02%)	0/103 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 15.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Gonal-f® Plus Pergoveris®	Pergoveris®
	Affected/At Risk (%)	Affected/At Risk (%)
Total	31/99 (31.31%)	32/103 (31.07%)
Cardiac disorders		
Extrasystoles [A] *	1/99 (1.01%)	0/103 (0%)
Ear and labyrinth disorders		
Vertigo [A] *	0/99 (0%)	1/103 (0.97%)
Eye disorders		
Myopia [A] *	1/99 (1.01%)	0/103 (0%)
Gastrointestinal disorders		
Abdominal discomfort [A] *	1/99 (1.01%)	0/103 (0%)
Abdominal distension [A] *	2/99 (2.02%)	2/103 (1.94%)
Abdominal pain [A] *	6/99 (6.06%)	4/103 (3.88%)

	Gonal-f® Plus Pergoveris®	Pergoveris®
	Affected/At Risk (%)	Affected/At Risk (%)
Abdominal pain lower [A] *	2/99 (2.02%)	2/103 (1.94%)
Abdominal pain upper [A] *	1/99 (1.01%)	0/103 (0%)
Constipation [A] *	0/99 (0%)	1/103 (0.97%)
Dental caries [A] *	1/99 (1.01%)	0/103 (0%)
Diarrhoea [A] *	1/99 (1.01%)	1/103 (0.97%)
Dyspepsia [A] *	1/99 (1.01%)	0/103 (0%)
Flatulence [A] *	1/99 (1.01%)	2/103 (1.94%)
Lip pruritus [A] *	1/99 (1.01%)	0/103 (0%)
Nausea [A] *	1/99 (1.01%)	3/103 (2.91%)
General disorders		
Fatigue [A] *	0/99 (0%)	2/103 (1.94%)
Injection site induration [A] *	0/99 (0%)	1/103 (0.97%)
Infections and infestations		
Escherichia vaginitis [A] *	1/99 (1.01%)	0/103 (0%)
Eye infection viral [A] *	0/99 (0%)	1/103 (0.97%)
Nasopharyngitis [A] *	2/99 (2.02%)	6/103 (5.83%)
Oral herpes [A] *	1/99 (1.01%)	1/103 (0.97%)
Vaginitis bacterial [A] *	1/99 (1.01%)	0/103 (0%)
Injury, poisoning and procedural complications		
Procedural pain [A] *	1/99 (1.01%)	1/103 (0.97%)
Investigations		
Oestradiol increased [A] *	0/99 (0%)	1/103 (0.97%)
Waist circumference increased [A] *	2/99 (2.02%)	0/103 (0%)

	Gonal-f® Plus Pergoveris®	Pergoveris®
	Affected/At Risk (%)	Affected/At Risk (%)
Weight increased [A] *	0/99 (0%)	1/103 (0.97%)
Musculoskeletal and connective tissue disorders		
Back pain [A] *	1/99 (1.01%)	1/103 (0.97%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Fibroadenoma of breast [A] *	0/99 (0%)	1/103 (0.97%)
Nervous system disorders		
Headache [A] *	14/99 (14.14%)	13/103 (12.62%)
Migraine [A] *	1/99 (1.01%)	0/103 (0%)
Somnolence [A] *	1/99 (1.01%)	2/103 (1.94%)
Syncope [A] *	0/99 (0%)	1/103 (0.97%)
Pregnancy, puerperium and perinatal conditions		
Abortion missed [A] *	1/99 (1.01%)	0/103 (0%)
Abortion spontaneous [A] *	0/99 (0%)	1/103 (0.97%)
Renal and urinary disorders		
Renal colic [A] *	1/99 (1.01%)	0/103 (0%)
Reproductive system and breast disorders		
Adnexa uteri pain [A] *	2/99 (2.02%)	2/103 (1.94%)
Breast pain [A] *	1/99 (1.01%)	1/103 (0.97%)
Breast tenderness [A] *	1/99 (1.01%)	0/103 (0%)
Dysmenorrhoea [A] *	3/99 (3.03%)	2/103 (1.94%)
Menopausal symptoms [A] *	1/99 (1.01%)	0/103 (0%)
Ovarian hyperstimulation syndrome [A] *	3/99 (3.03%)	4/103 (3.88%)
Pelvic pain [A] *	0/99 (0%)	1/103 (0.97%)

	Gonal-f® Plus Pergoveris®	Pergoveris®
	Affected/At Risk (%)	Affected/At Risk (%)
Vaginal haemorrhage [A] *	3/99 (3.03%)	3/103 (2.91%)
Vulvovaginal burning sensation [A] *	2/99 (2.02%)	0/103 (0%)
Vulvovaginal pain [A] *	0/99 (0%)	1/103 (0.97%)
Vulvovaginal pruritus [A] *	2/99 (2.02%)	0/103 (0%)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain [A] *	2/99 (2.02%)	1/103 (0.97%)
Skin and subcutaneous tissue disorders		
Dermatitis allergic [A] *	0/99 (0%)	1/103 (0.97%)
Dermatitis contact [A] *	1/99 (1.01%)	0/103 (0%)
Dry skin [A] *	1/99 (1.01%)	0/103 (0%)
Eczema [A] *	0/99 (0%)	1/103 (0.97%)
Erythema [A] *	1/99 (1.01%)	0/103 (0%)
Pruritus [A] *	1/99 (1.01%)	1/103 (0.97%)
Rash [A] *	1/99 (1.01%)	0/103 (0%)
Xeroderma [A] *	0/99 (0%)	1/103 (0.97%)
Vascular disorders		
Hot flush [A] *	0/99 (0%)	1/103 (0.97%)
Hypertension [A] *	3/99 (3.03%)	0/103 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 15.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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