ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 01/20/2014

ClinicalTrials.gov ID: NCT00553514

Study Identification

Unique Protocol ID:	27818
Brief Title:	AS900672-Enriched in Ovulation Induction
Official Title:	A Phase II, Multicentre, Randomised, Assessor-blinded, Active-comparator, Parallel-group Dose Finding Trial to Evaluate AS900672-enriched Versus Follitropin Alfa (GONAL-f®) in Oligo-anovulatory Infertile Women Undergoing Ovulation Induction (OI)
Secondary IDs:	

Study Status

Record Verification:	January 2014
Overall Status:	Terminated
Study Start:	December 2007
Primary Completion:	March 2009 [Actual]
Study Completion:	March 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Merck KGaA
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 8 Oct 2007 Board Name: The Epworth Healthcare Human Researchand Ethics Committee (HREC) Board Affiliation: The Epworth Healthcare Human Researchand Ethics Committee (HREC) Phone: + 614 9426 6666 Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Argentina: Human Research Bioethics Committee Australia: Human Research Ethics Committee Belgium: Institutional Review Board Chile: Instituto de Salud Pública de Chile Denmark: Ethics Committee France: Institutional Ethical Committee Germany: Ethics Commission Israel: Ethics Commission Italy: Ethics Committee Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Spain: Comité Ético de Investigación Clínica Sweden: Regional Ethical Review Board Turkey: Ethics Committee United Kingdom: Research Ethics Committee

Study Description

Brief Summary:	This is a Phase 2, interventional, multi-center, randomized, assessor-blind, active-comparator, dose-finding study to evaluate a new investigational long-acting follicle stimulating hormone (FSH) in oligo-anovulatory women undergoing ovulation induction (OI). This study will compare 4 doses of the investigational drug versus a currently marketed drug follitropin alfa (Gonal-f ®) prefilled pen with regards to ovulation rate.
Detailed Description:	The study was terminated after Merck Serono had taken the decision not to pursue the development of AS900672-enriched in ovulation induction (OI). This decision was not related to any safety or efficacy concerns over the use of AS900672-Enriched in OI.

Conditions

Conditions:	Ovulation Induction
Keywords:	Infertility Oligo-anovulation GONAL-f®

AS900672-Enriched
hyperglycosylated recombinant human follicle stimulating hormone (r-hFSH)

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	5
Masking:	Single Blind (Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	71 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: AS900672-Enriched 10 mcg	Drug: AS900672-Enriched 10 microgram (mcg) Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 mcg will be administered subcutaneously on Stimulation Day 1 (S1). Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Hyperglycosylated r-hFSH Drug: Follitropin alfa 75 international unit (IU) Follitropin alfa (Gonal-f®) 75 IU will be administered subcutaneously once daily from S1 up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. Subjects who will be receiving AS900672-Enriched 10, 20, 30 and 40 mcg will also receive daily dose of follitropin alfa 75 IU subcutaneously from Stimulation Day 7 (S7) up to S14. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Gonal-f® • Follicle stimulating hormone (FSH)

Arms	Assigned Interventions
	Drug: Recombinant human chorionic gonadotropin (r-hCG) Recombinant human chorionic gonadotropin (r-hCG) will be administered as a single dose of 250 mcg subcutaneously, when follicular response is adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm).
Experimental: AS900672-Enriched 20 mcg	Drug: AS900672-Enriched 20 mcg Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg will be administered subcutaneously on S1. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Hyperglycosylated r-hFSH Drug: Follitropin alfa 75 international unit (IU) Follitropin alfa (Gonal-f®) 75 IU will be administered subcutaneously once daily from S1 up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. Subjects who will be receiving AS900672-Enriched 10, 20, 30 and 40 mcg will also receive daily dose of follitropin alfa 75 IU subcutaneously from Stimulation Day 7 (S7) up to S14. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Gonal-f® • Follicle stimulating hormone (FSH) Drug: Recombinant human chorionic gonadotropin (r-hCG) Recombinant human chorionic gonadotropin (r-hCG) will be administered as a single dose of 250 mcg subcutaneously, when follicular response is adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm).
Experimental: AS900672-Enriched 30 mcg	Drug: AS900672-Enriched 30 mcg Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg will be administered subcutaneously on S1. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Hyperglycosylated r-hFSH Drug: Follitropin alfa 75 international unit (IU)

Arms	Assigned Interventions
	Follitropin alfa (Gonal-f®) 75 IU will be administered subcutaneously once daily from S1 up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. Subjects who will be receiving AS900672-Enriched 10, 20, 30 and 40 mcg will also receive daily dose of follitropin alfa 75 IU subcutaneously from Stimulation Day 7 (S7) up to S14. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Gonal-f® • Follicle stimulating hormone (FSH) Drug: Recombinant human chorionic gonadotropin (r-hCG) Recombinant human chorionic gonadotropin (r-hCG) will be administered as a single dose of 250 mcg subcutaneously, when follicular response is adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm).
Experimental: AS900672-Enriched 40 mcg	Drug: AS900672-Enriched 40 mcg Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg will be administered subcutaneously on S1. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Hyperglycosylated r-hFSH Drug: Follitropin alfa 75 international unit (IU) Follitropin alfa (Gonal-f®) 75 IU will be administered subcutaneously once daily from S1 up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. Subjects who will be receiving AS900672-Enriched 10, 20, 30 and 40 mcg will also receive daily dose of follitropin alfa 75 IU subcutaneously from Stimulation Day 7 (S7) up to S14. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Gonal-f® • Follicle stimulating hormone (FSH) Drug: Recombinant human chorionic gonadotropin (r-hCG) Recombinant human chorionic gonadotropin (r-hCG) will be administered as a single dose of 250 mcg subcutaneously, when follicular response is adequate (that is, less than or equal to [=<] 3 follicles with a mean

Arms	Assigned Interventions
	diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm).
Active Comparator: Follitropin alfa 75 IU	Drug: Follitropin alfa 75 international unit (IU) Follitropin alfa (Gonal-f®) 75 IU will be administered subcutaneously once daily from S1 up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. Subjects who will be receiving AS900672-Enriched 10, 20, 30 and 40 mcg will also receive daily dose of follitropin alfa 75 IU subcutaneously from Stimulation Day 7 (S7) up to S14. Duration of treatment cycle will be up to adequate follicular response received or maximum of 14 days. Other Names: • Gonal-f® • Follicle stimulating hormone (FSH) Drug: Recombinant human chorionic gonadotropin (r-hCG) Recombinant human chorionic gonadotropin (r-hCG) will be administered as a single dose of 250 mcg subcutaneously, when follicular response is adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm).

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 36 Years

Gender: Female

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Oligo-anovulation defined by a menstrual period of 35 days to 6 months
- Spontaneous menses or a positive response to progestin within the prior 6 months or response to clomiphene citrate evidenced by ovulation within the prior 6 months
- Age between 18 and 36 years, inclusive, at time of informed consent signature
- Body mass index (BMI) 18 to 30 kilogram per square meter (kg/m^2), inclusive

- No clinically significant abnormalities in serum thyroid stimulating hormone (TSH), dehydroepiandrosterone (DHEA-S), prolactin, and FSH levels in the early follicular phase. Subjects low TSH level who receive replacement therapy could be enrolled at the discretion of the investigator if local laboratory results (thyroxine [T4]) demonstrated satisfactory thyroid function. Subjects receiving stable dose of dopamine agonists could be enrolled at the discretion of the investigator if local laboratory results demonstrated adequate control of prolactin levels
- No clinically significant abnormalities in fasting glucose and fasting insulin levels
- Normal uterine cavity and presence of at least one ovary with ipsilateral patent fallopian tube, as determined by means of hysterosalpingography, laparoscopy, hysteroscopy or combination of these procedures within the prior 3 years
- Papanicolaou (PAP) smear test without clinically significant abnormalities within 6 months prior to the first screening procedure. If PAP smear is not done, it must be performed as part of screening procedures
- Negative pregnancy test prior to randomization
- Male partner with semen analysis demonstrating adequacy for insemination via intercourse and/or intrauterine insemination (IUI) within 6 months prior to the first screening procedure. If semen analysis is not done, it must be performed as part of screening procedures
- Willing and able to comply with all protocol procedures, including pregnancy and neonatal follow-up
- Voluntary provision of written informed consent, prior to any trial-related procedure that is not part of normal medical care, with the understanding that the subject could withdraw consent at any time without prejudice to her future medical care, including willingness to provide follow-up information on babies born as part of this trial

Exclusion Criteria:

- History of >=2 consecutive gonadotrophin stimulation cycles that did not lead to ovulation
- History of clomiphene citrate stimulation cycles of which none lead to ovulation
- Prior excessive response to gonadotrophin stimulation, defined as the development of at least 4 mature follicles (greater than [>]17 mm) or cancellation of the OI cycle due to excessive follicular response after treatment with FSH at a dose of less than 75 IU/day
- Previous severe ovarian hyperstimulation syndrome (OHSS)
- Administration of any gonadotrophin, clomiphene citrate, gonadotrophin releasing hormone (GnRH) analogue, tamoxifen or aromatase inhibitors within the prior 30 days
- Laparoscopic ovarian drilling and/or ovarian cauterization within the prior 6 months
- Any contraindication to pregnancy and/or to carrying pregnancy to term
- A clinical pregnancy that ended in a miscarriage within the prior 3 months
- History of >=3 consecutive miscarriages, due to any cause
- Abnormal gynecological bleeding of undetermined origin
- Clinically significant abnormal findings of the uterine cavity evident on a transvaginal pelvic ultrasound performed during screening
- Presence of endometriosis, Grade III - IV or requiring treatment
- Ovarian cyst with a mean diameter of >25 mm on the day of randomization
- History or suspicion of ovarian, uterine or mammary cancer
- Adrenal congenital hyperplasia, partial or complete enzymatic block
- Use of metformin or other insulin sensitizing agents related to infertility within the prior 2 months
- Known allergy or hypersensitivity to human gonadotrophin preparations or to compounds that are structurally similar to any of the other medications administered during the trial
- Any contra-indication to gonadotrophin therapy
- Known or suspected infection with human immunodeficiency virus (HIV), Hepatitis B or C in the trial subject or her male partner

- Any active substance abuse or history of drug, medication or alcohol abuse within 5 years
- Smoker consuming more than 5 cigarettes per day
- Serum testosterone (central laboratory) that is suggestive of ovarian tumor
- Previously randomized in this trial or participation in another investigational drug clinical trial within the prior 3 months
- Any medical condition, which in the judgment of the investigator may interfere with the absorption, distribution, metabolism or excretion of r-hFSH
- Clinically significant concurrent disease (including diabetes mellitus and autoimmune diseases) that would compromise subject safety or interfere with the study assessments or clinically significant abnormal laboratory finding

Contacts/Locations

Study Officials: Antonio Pellicer, Professor Dr
Study Principal Investigator
IVI Valencia

Locations: Switzerland
Merck Serono S.A.
Geneva, Switzerland, 1202

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Overall Study

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Started	14	14	15	13	15
Completed	6	6	9	6	8
Not Completed	8	8	6	7	7
Protocol deviation	0	0	0	1	0
Lack of ovarian response	4	5	5	5	6
Ovarian hyperstimulation syndrome risk	3	0	1	0	0
Risk of multiple pregnancy	0	2	0	1	0
Unspecified	1	1	0	0	1

Baseline Characteristics

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

	Description
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Baseline Measures

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU	Total
Number of Participants	14	14	15	13	15	71
Age, Continuous [units: years] Median (Full Range)	29.5 (23 to 36)	31.5 (23 to 36)	28.0 (26 to 35)	30.0 (23 to 36)	30.0 (23 to 34)	30 (23 to 36)
Gender, Male/Female [units: participants]						
Female	14	14	15	13	15	71
Male	0	0	0	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Ovulation
Measure Description	Ovulation was defined as a mid-luteal phase progesterone (P4) level >= 30 nanomole per liter (nmol/L) (10 nanogram per milliliter [ng/mL]). In the absence of a positive progesterone response, clinical pregnancy was also considered as evidence of ovulation.
Time Frame	Mid-luteal phase progesterone assessed 5-10 days or clinical pregnancy 35-42 days after recombinant human chorionic gonadotropin (r-hCG) administration day (end of stimulation cycle [approximately 14 days])
Safety Issue?	No

Analysis Population Description

Per Protocol (PP) population included all the randomized participants who were without a medically relevant protocol deviation. 'N' (number of participants analyzed) signifies participants who were evaluable for this measure.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Measured Values

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Number of Participants Analyzed	13	13	13	12	13
Percentage of Participants With Ovulation [units: Percentage of participants]	46.2	46.2	38.5	33.3	53.8

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Clinical Pregnancy
Measure Description	Clinical pregnancy was defined as the presence of one or more fetal sacs with fetal heart activity on the Day 35-42 post r-hCG ultrasound examination.
Time Frame	Day 35-42 post r-hCG administration day (end of stimulation cycle [approximately 14 days])
Safety Issue?	No

Analysis Population Description

PP population included all the randomized participants who were without a medically relevant protocol deviation. 'N' (number of participants analyzed) signifies participants who were evaluable for this measure.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

	Description
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Measured Values

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Number of Participants Analyzed	13	13	13	12	13
Percentage of Participants With Clinical Pregnancy [units: Percentage of participants]	23.1	0.0	7.7	16.7	0.0

3. Secondary Outcome Measure:

Measure Title	Duration of Ovarian Stimulation
Measure Description	Ovarian stimulation included from first dose of study drug on S1 until day on which r-hCG was administered (r-hCG day).
Time Frame	Stimulation Day 1 (S1) up to r-hCG administration day (end of stimulation cycle [approximately 14 days])
Safety Issue?	No

Analysis Population Description

PP population included all the randomized participants who were without a medically relevant protocol deviation. 'N' (number of participants analyzed) signifies participants who were evaluable for this measure.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Measured Values

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Number of Participants Analyzed	13	13	13	12	13
Duration of Ovarian Stimulation	10.0 (5.3)	11.8 (3.4)	14.0 (1.4)	10.8 (3.7)	10.6 (3.2)

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
[units: Days] Mean (Standard Deviation)					

4. Secondary Outcome Measure:

Measure Title	Duration of Supplemental Follitropin Alfa Treatment
Measure Description	
Time Frame	Stimulation Day 7 (S7) up to r-hCG administration day (end of stimulation cycle [approximately 14 days])
Safety Issue?	No

Analysis Population Description

PP population included all the randomized participants who were without a medically relevant protocol deviation. 'N' (number of participants analyzed) signifies participants who were evaluable for this measure.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

	Description
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Measured Values

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Number of Participants Analyzed	10	12	13	11	11
Duration of Supplemental Follitropin Alfa Treatment [units: Days] Mean (Standard Deviation)	6.6 (1.4)	6.6 (1.4)	7.7 (1.5)	5.6 (2.2)	5.5 (2.7)

5. Secondary Outcome Measure:

Measure Title	Cumulative Dose of Supplemental Follitropin Alfa Administered
Measure Description	
Time Frame	Stimulation Day 7 (S7) up to r-hCG administration day (end of stimulation cycle [approximately 14 days])
Safety Issue?	No

Analysis Population Description

PP population included all the randomized participants who were without a medically relevant protocol deviation. 'N' (number of participants analyzed) signifies participants who were evaluable for this measure.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Measured Values

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Number of Participants Analyzed	10	12	13	11	10
Cumulative Dose of Supplemental Follitropin Alfa Administered	476.3 (122.5)	493.8 (108.3)	556.7 (134.2)	398.9 (167.9)	397.5 (226.5)

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
[units: IU] Mean (Standard Deviation)					

6. Secondary Outcome Measure:

Measure Title	Number of Follicles With Mean Diameter Less Than (<) 11 Millimeter (mm) and Greater Than or Equal to (>=) 11 mm
Measure Description	
Time Frame	Stimulation Day 5 (S5), S7 and r-hCG administration day (end of stimulation cycle [approximately 14 days])
Safety Issue?	No

Analysis Population Description

PP population included all the randomized participants who were without a medically relevant protocol deviation. 'N' (number of participants analyzed) signifies participants who were evaluable for this measure. 'n' signifies number of participants who were evaluable for specified categories at different time points.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

	Description
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Measured Values

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
Number of Participants Analyzed	12	12	13	12	13
Number of Follicles With Mean Diameter Less Than (<) 11 Millimeter (mm) and Greater Than or Equal to (>=) 11 mm [units: Follicles] Mean (Standard Deviation)					
< 11 mm on S5 (n=12,12,12,12,13)	23.6 (13.8)	28.7 (29.4)	23.2 (6.7)	20.9 (16.7)	21.3 (13.7)
< 11 mm on S7 (n=12,12,13,12,12)	22.8 (12.6)	27.2 (30.9)	21.0 (8.9)	21.3 (17.3)	22.0 (16.7)
< 11 mm on r-hCG Day (n=5,6,7,6,7)	15.6 (7.3)	11.7 (9.2)	18.4 (12.1)	18.7 (15.0)	14.9 (12.4)
>= 11 mm on S5 (n=12,8,7,11,8)	1.5 (2.2)	0.0 (0.0)	1.6 (1.9)	2.8 (3.1)	0.8 (0.9)
>= 11 mm on S7 (n=11,9,7,11,11)	3.4 (6.2)	0.2 (0.7)	2.6 (3.5)	2.8 (2.4)	1.8 (2.3)
>= 11 mm on r-hCG Day (n=5,6,8,6,8)	2.6 (0.9)	2.5 (1.9)	2.5 (1.3)	1.8 (0.8)	2.9 (1.8)

Reported Adverse Events

Time Frame	Stimulation Day 1 (S1) up to Day 35-42 post r-hCG administration day (end of stimulation cycle [approximately 14 days])
Additional 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.

Reporting Groups

	Description
AS900672-Enriched 10 mcg	Single injection of AS900672-Enriched (hyperglycosylated recombinant human follicle stimulating hormone [r-hFSH]), 10 microgram (mcg) administered subcutaneously on Stimulation day 1 (S1) followed by a daily dose of follitropin alfa 75 international unit (IU) subcutaneously starting from Stimulation Day 7 (S7) up to Stimulation Day 14 (S14) based upon ovarian response, until recombinant human chorionic gonadotropin (r-hCG) administration day. When follicular response was adequate (that is, less than or equal to [=<] 3 follicles with a mean diameter of greater than or equal to [>=] 14 millimeter [mm], and one or two of these follicles with a diameter of >= 17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 20 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 20 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 30 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 30 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.
AS900672-Enriched 40 mcg	Single injection of AS900672-Enriched (hyperglycosylated r-hFSH), 40 mcg administered subcutaneously on S1 followed by a daily dose of follitropin alfa 75 IU subcutaneously starting from S7 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

	Description
Follitropin Alfa 75 IU	Follitropin alfa (Gonal-f®) 75 IU administered subcutaneously once daily from S1 up to S14 based upon ovarian response, until r-hCG administration day. When follicular response was adequate (that is, =< 3 follicles with a mean diameter of >=14 mm, and one or two of these follicles with a diameter of >=17 mm), ovulation was triggered by single 250 mcg subcutaneous r-hCG injection. Duration of treatment cycle was up to adequate follicular response received or maximum of 14 days.

Serious Adverse Events

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/14 (0%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	0/15 (0%)

Other Adverse Events

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

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	7/14 (50%)	3/14 (21.43%)	6/15 (40%)	4/13 (30.77%)	7/15 (46.67%)
Eye disorders					
Eye pain [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)
Gastrointestinal disorders					
Abdominal distension [A] *	1/14 (7.14%)	1/14 (7.14%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)
Abdominal pain [A] *	1/14 (7.14%)	1/14 (7.14%)	0/15 (0%)	1/13 (7.69%)	2/15 (13.33%)
Abdominal pain upper [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)
Abdominal tenderness [A] *	1/14 (7.14%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Diarrhoea [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	1/15 (6.67%)
Gastrointestinal pain [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)
Nausea [A] *	1/14 (7.14%)	1/14 (7.14%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Stomach discomfort [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
General disorders					
Fatigue [A] *	1/14 (7.14%)	1/14 (7.14%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Infections and infestations					
Gastroenteritis [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	1/15 (6.67%)
Nasopharyngitis [A] *	0/14 (0%)	1/14 (7.14%)	0/15 (0%)	1/13 (7.69%)	1/15 (6.67%)
Tonsillitis [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	1/15 (6.67%)
Upper respiratory tract infection [A] *	0/14 (0%)	0/14 (0%)	1/15 (6.67%)	0/13 (0%)	0/15 (0%)
Urinary tract infection [A] *	1/14 (7.14%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Injury, poisoning and procedural complications					
Procedural pain [A] *	0/14 (0%)	1/14 (7.14%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Musculoskeletal and connective tissue disorders					
Pain in extremity [A] *	1/14 (7.14%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Nervous system disorders					
Dizziness [A] *	1/14 (7.14%)	0/14 (0%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)
Headache [A] *	2/14 (14.29%)	1/14 (7.14%)	3/15 (20%)	3/13 (23.08%)	2/15 (13.33%)
Migraine [A] *	0/14 (0%)	0/14 (0%)	1/15 (6.67%)	0/13 (0%)	0/15 (0%)
Syncope vasovagal [A] *	0/14 (0%)	0/14 (0%)	1/15 (6.67%)	0/13 (0%)	0/15 (0%)
Reproductive system and breast disorders					
Adnexa uteri pain [A] *	1/14 (7.14%)	0/14 (0%)	1/15 (6.67%)	0/13 (0%)	0/15 (0%)
Breast pain [A] *	0/14 (0%)	1/14 (7.14%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Breast tenderness [A] *	0/14 (0%)	1/14 (7.14%)	1/15 (6.67%)	0/13 (0%)	0/15 (0%)
Genital haemorrhage [A] *	1/14 (7.14%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	0/15 (0%)

	AS900672-Enriched 10 mcg	AS900672-Enriched 20 mcg	AS900672-Enriched 30 mcg	AS900672-Enriched 40 mcg	Follitropin Alfa 75 IU
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Ovarian hyperstimulation syndrome [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	1/13 (7.69%)	0/15 (0%)
Vaginal discharge [A] *	0/14 (0%)	1/14 (7.14%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Vaginal pain [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	2/15 (13.33%)
Vulvovaginal pruritus [A] *	1/14 (7.14%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	0/15 (0%)
Respiratory, thoracic and mediastinal disorders					
Rhinorrhoea [A] *	0/14 (0%)	0/14 (0%)	0/15 (0%)	0/13 (0%)	1/15 (6.67%)
Skin and subcutaneous tissue disorders					
Urticaria [A] *	0/14 (0%)	0/14 (0%)	1/15 (6.67%)	0/13 (0%)	0/15 (0%)

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

Limitations and Caveats

The study was terminated after Merck Serono had taken the decision not to pursue the development of AS900672-enriched in ovulation induction

More Information

Certain Agreements:

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

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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