Corifollitropin Alfa in Participants Undergoing Repeated Controlled Ovarian Stimulation (COS) Cycles Using a Multiple Dose Gonadatropin Releasing Hormone (GnRH) Antagonist Protocol (Study 38825) (P05714) (Trust)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00696878

First received: June 11, 2008
Last updated: May 20, 2015
Last verified: May 2015
History of Changes

Purpose

The objective of the trial is to assess the non-immunogenicity and safety of corifollitropin alfa (also known as Org 36286, SCH 900962 and MK-8962) in participants undergoing repeated COS cycles using a multiple dose GnRH antagonist protocol.

Condition	Intervention	Phase
In Vitro Fertilization	Drug: Corifollitropin alfa Biological: FSH Biological: GnRH antagonist Biological: (rec)hCG Drug: Progesterone	Phase 3

Study Type: Interventional
Study Design: Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase III, Uncontrolled Trial to Assess the Non-immunogenicity and Safety of Org 36286 in Patients Undergoing Repeated Controlled Ovarian Stimulation Cycles Using a Multiple Dose GnRH Antagonist Protocol

Resource links provided by NLM:

MedlinePlus related topics: Hormones

Drug Information available for: Progesterone

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Percentage of Participants With Clinically Relevant Immunogenicity [Time Frame: Pre-dose (Stimulation Day 1) and up to approximately 40 days post dose in each treatment cycle] [Designated as safety issue: Yes]

  Serum samples obtained pre-dose and at 2 weeks after embryo transfer (ET), or at cycle discontinuation and 2-3 weeks after cycle discontinuation if cycle was stopped before ET was performed, were analyzed for presence of anti-corifollitropin alfa antibodies using screening and confirmatory tests. If a participant was confirmed to have anti-corifollitropin alfa antibody present in a post dose sample according to these tests, review of adverse events (AEs) in the participant was performed. The sample was also tested to evaluate whether the antibody appeared to have neutralizing activity that would interfere with the study drug biological effect. A participant was determined to have clinically relevant immunogenicity if the participant had a confirmed post dose anti-corifollitropin alfa antibody test result accompanied by clinical signs of immunogenicity (e.g., hypersensitivity reaction), considering also the results of the test for neutralizing activity of any antibody present.

- Local Tolerance at Injection Site: Number of Participants With no Event of Itching and With Mild, Moderate and Severe Itching in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle] [Designated as safety issue: Yes]

  At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of itching. A participant with an event was counted once in this analysis.

- Local Tolerance at Injection Site: Number of Participants With no Event of Pain and With Mild, Moderate and Severe Pain in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle] [Designated as safety issue: Yes]

  At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of pain. A participant with an event was counted once in this analysis.

- Local Tolerance at Injection Site: Number of Participants With no Event of Redness and With Mild, Moderate and Severe Redness in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle] [Designated as safety issue: Yes]

  At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of redness. A participant with an event was counted once in this analysis.

- Local Tolerance at Injection Site: Number of Participants With no Event of Swelling and With Mild, Moderate and Severe Swelling in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle] [Designated as safety issue: Yes]

  At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of swelling. A participant with an event was counted once in this analysis.

- Local Tolerance at Injection Site Overall Summary: Number of Participants With no Local Tolerance Event (Itching, Pain, Redness or Swelling) and With a Mild, Moderate and Severe Local Tolerance Event in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle] [Designated as safety issue: Yes]

  At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results considering the occurrence of any of the defined local tolerance events. A participant with an event was counted once in this analysis.

- Number of Participants With AEs [Time Frame: Up to approximately 26 months after first dose of corifollitropin alfa] [Designated as safety issue: Yes]

  An AE was defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

- Number of Participants With Serious AEs (SAEs) [Time Frame: Up to approximately 26 months after first dose of corifollitropin alfa] [Designated as safety issue: Yes]

  An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening, required in-patient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, or was a congenital anomaly/birth defect. SAEs that occurred in fetuses or infants during the study period are included in this summary of SAEs, and are allocated to the associated study participant who was administered corifollitropin alfa.

- Number of Participants With Moderate to Severe Ovarian Hyperstimulation Syndrome (OHSS) [Time Frame: Up to approximately 1 month after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle]
  [Designated as safety issue: Yes]

  OHSS was classified on study based on a slightly modified WHO Scientific Group (1973) classification: Grade I (mild) = characterized by excessive steroid secretion and ovarian enlargement (5-7 cm). Abdominal discomfort, including abdominal pain, is present. Grade II (moderate) = characterized by distinct ovarian cysts (ovary size 8-10 cm), accompanied by abdominal pain and tension, nausea, vomiting, diarrhea. Grade III (severe) = characterized by enlarged cystic ovaries (ovary size >10 cm), accompanied by ascites and occasionally hydrothorax. Abdominal tension and pain may be severe. Pronounced hydrothorax together with an abdominal cavity filled with cysts and fluid elevating the diaphragm may cause severe breathing difficulties. Large quantities of fluid inside the cysts and in the peritoneal and pleural cavities cause haemoconcentration and increased blood viscosity. In rare cases, the syndrome may further be complicated by the occurrence of thromboembolic phenomena.

Secondary Outcome Measures:

- Amount of (Rec)FSH Needed From Stimulation Day 8 Onwards to Reach the Criterion for Administration of (Rec)hCG
  [Time Frame: Stimulation Day 8 to day of (rec)hCG administration (approximately Stimulation Day 10), within a treatment cycle]
  [Designated as safety issue: No]

  Beginning on Stimulation Day 8 of each treatment cycle, (rec)FSH was administered daily until the criteria for administration of (rec)hCG (presence of 3 follicles ≥17 mm documented by ultrasonography) was reached. The total amount of (rec)FSH administered in each participant to reach the criteria for (rec)hCG administration was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 1 [Time Frame: Stimulation Day 1 in Treatment Cycle 1] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 2 [Time Frame: Stimulation Day 1 in Treatment Cycle 2] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 3 [Time Frame: Stimulation Day 1 in Treatment Cycle 3] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 1 [Time Frame: Stimulation Day 5 or 6 in Treatment Cycle 1] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 2 [Time Frame: Stimulation Day 5 or 6 in Treatment Cycle 2] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 3 [Time Frame: Stimulation Day 5 or 6 in Treatment Cycle 3] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 1 [Time Frame: Stimulation Day 8 in Treatment Cycle 1] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During

Treatment Cycle 2 [Time Frame: Stimulation Day 8 in Treatment Cycle 2] [Designated as safety issue: No]

For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 3 [Time Frame: Stimulation Day 8 in Treatment Cycle 3] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 1 [Time Frame: Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 1] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on the day of (rec)hCG administration during the treatment cycle was recorded.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 2 [Time Frame: Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 2] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on the day of (rec)hCG administration during the treatment cycle was recorded.

- Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 3 [Time Frame: Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 3] [Designated as safety issue: No]

  For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on the day of (rec)hCG administration during the treatment cycle was recorded.

- Number of Oocytes Retrieved in a Participant Among Entire Study Population [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), within a treatment cycle] [Designated as safety issue: No]

  Oocyte retrieval, also known as oocyte pick-up, is a technique used in in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) in order to remove oocytes from the ovary of the female, enabling fertilization outside the body. The number of oocytes retrieved, per participant, is summarized.

- Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 1 [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 1] [Designated as safety issue: No]

  This measure summarizes results of assessment of the quality of oocytes performed following oocyte retrieval, among participants scheduled for ICSI in Treatment Cycle 1. For oocytes obtained from each participant, the number in each of 3 stages of oocyte development were determined. The earliest phase is the germinal vesicles stage, during which the immature oocyte appears as a large vesicular nucleus. Metaphase I is an intermediate stage during which the vesicles have broken down and the polar body has not yet formed; the oocyte is still immature. Metaphase II is the mature oocyte and is indicated by the presence of the polar body. Rating of quality for usefulness in ICSI follows the order metaphase II (best quality), metaphase I (lesser quality) and germinal vesicles stage (poorest quality). Only metaphase II oocytes can be fertilized. Metaphase I oocytes can develop in vitro to metaphase II oocytes. Germinal vesicles stage oocytes are the least useful for ICSI procedures.

- Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 2 [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 2] [Designated as safety issue: No]

  This measure summarizes results of assessment of the quality of oocytes performed following oocyte retrieval, among participants scheduled for ICSI in Treatment Cycle 2. For oocytes obtained from each participant, the number in each of 3 stages of oocyte development were determined. The earliest phase is the germinal vesicles stage, during which the immature oocyte appears as a large vesicular nucleus. Metaphase I is an intermediate stage during which the vesicles have broken down and the polar body has not yet formed; the oocyte is still immature. Metaphase II is the mature oocyte and is indicated by the presence of the polar body. Rating of quality for usefulness in ICSI follows the order metaphase II (best quality), metaphase I (lesser quality) and germinal vesicles stage (poorest quality). Only metaphase II oocytes can be fertilized. Metaphase I oocytes can develop in vitro to metaphase II oocytes. Germinal vesicles stage oocytes are the least useful for ICSI procedures.

- Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 3 [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 3] [Designated as safety issue: No]

  This measure summarizes results of assessment of the quality of oocytes performed following oocyte retrieval, among participants scheduled

for ICSI in Treatment Cycle 3. For oocytes obtained from each participant, the number in each of 3 stages of oocyte development were determined. The earliest phase is the germinal vesicles stage, during which the immature oocyte appears as a large vesicular nucleus. Metaphase I is an intermediate stage during which the vesicles have broken down and the polar body has not yet formed; the oocyte is still immature. Metaphase II is the mature oocyte and is indicated by the presence of the polar body. Rating of quality for usefulness in ICSI follows the order metaphase II (best quality), metaphase I (lesser quality) and germinal vesicles stage (poorest quality). Only metaphase II oocytes can be fertilized. Metaphase I oocytes can develop in vitro to metaphase II oocytes. Germinal vesicles stage oocytes are the least useful for ICSI procedures.

- Number of Fertilized Oocytes Obtained in Treatment Cycle 1 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]
  [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure, by category of number of pronuclei (PN) present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained in Treatment Cycle 2 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]
  [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained in Treatment Cycle 3 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]
  [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 1 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]
  [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ICSI procedure that were cryopreserved (frozen) for possible later use, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 2 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]
  [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ICSI procedure that were cryopreserved (frozen) for possible later use, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 3 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]
  [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ICSI procedure that were cryopreserved (frozen) for possible later use, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 1 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1] [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure that were used for embryo development, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 2 [Time Frame: 16-18 hours after start of

IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2] [Designated as safety issue: No]

This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure that were used for embryo development, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 3 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3] [Designated as safety issue: No]

  This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure that were used for embryo development, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).

- Fertilization Rate [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle] [Designated as safety issue: No]

  The fertilization rate (in percent) is defined as 100 times the ratio of the number of fertilized 2 PN oocytes obtained and the number of oocytes that was used for fertilization, per participant.

- Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 1 [Time Frame: Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1] [Designated as safety issue: No]

  At Day 3 after oocyte pick-up, embryos obtained from IVF or ISCI process for each participant were counted and quality was assessed. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 2 [Time Frame: Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2] [Designated as safety issue: No]

  At Day 3 after oocyte pick-up, embryos obtained from IVF or ISCI process for each participant were counted and quality was assessed. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 3 [Time Frame: Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3] [Designated as safety issue: No]

  At Day 3 after oocyte pick-up, embryos obtained from IVF or ISCI process for each participant were counted and quality was assessed. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number of Embryos Transferred [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle] [Designated as safety issue: No]

  ET is the procedure in which one or more embryos are placed in the uterus. The number of embryos transferred, per participant, is summarized.

- Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 1 [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1] [Designated as safety issue: No]

  The number of embryos transferred, for each participant, by category of number of "good quality" embryos transferred, is summarized. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 2 [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2] [Designated as safety issue: No]

  The number of embryos transferred, for each participant, by category of number of "good quality" embryos transferred, is summarized. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 3 [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3] [Designated as safety issue: No]

The number of embryos transferred, for each participant, by category of number of "good quality" embryos transferred, is summarized. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 1 [Time Frame: Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1] [Designated as safety issue: No]

  The number of embryos that were cryopreserved (frozen) for possible later use, for each participant, overall and by embryo quality categories, is summarized. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 2 [Time Frame: Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2] [Designated as safety issue: No]

  The number of embryos that were cryopreserved (frozen) for possible later use, for each participant, overall and by embryo quality categories, is summarized. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 3 [Time Frame: Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3] [Designated as safety issue: No]

  The number of embryos that were cryopreserved (frozen) for possible later use, for each participant, overall and by embryo quality categories, is summarized. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

- Implantation Rate for Participants With ET [Time Frame: Approximately 5-6 weeks after ET, within a treatment cycle] [Designated as safety issue: No]

  The implantation rate (in percent) is defined as 100 times the maximum number of gestational sacs as assessed by any ultrasound scan after ET divided by the number of embryos transferred per participant.

- Number of Participants With Biochemical Pregnancy, Clinical Pregnancy, Vital Pregnancy and Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: ≥14 days (for biochemical pregnancy), 5-6 weeks (for clinical pregnancy), 5-6 weeks to 10 weeks (for vital pregnancy) and 10 weeks up to 9 months (for ongoing pregnancy) after ET, within a treatment cycle] [Designated as safety issue: No]

  Biochemical pregnancy: Pregnancy proven by a biochemical pregnancy test using urine samples or serum samples collected at least 14 days after ET. Participants not having a positive biochemical pregnancy test result, but with an ultrasound scan showing at least one gestational sac were counted as having a biochemical pregnancy. Clinical pregnancy: Presence of at least one gestational sac as assessed by ultrasound scan. Vital pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan. Ongoing pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan at least 10 weeks after ET, or confirmed by live birth.

- Number of Participants With Singleton and Multiple Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: 10 weeks up to 9 months after ET, within a treatment cycle] [Designated as safety issue: No]

  Singleton pregnancy is a pregnancy in which one fetus develops in the uterus. Multiple pregnancy is a pregnancy in which more than one fetus develops simultaneously in the uterus. Ongoing pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan at least 10 weeks after ET, or confirmed by live birth.

- Number of Participants With Miscarriage Among Participants With Clinical Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: 5-6 weeks up to 9 months after ET, within a treatment cycle] [Designated as safety issue: No]

  Miscarriage: Loss of the fetus without induction or instrumentation, also known as "spontaneous abortion." Clinical pregnancy: Presence of at least one gestational sac as assessed by ultrasound scan.

- Number of Participants With Miscarriage Among Participants With Vital Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: 5-6 weeks up to 9 months after ET, within a treatment cycle] [Designated as safety issue: No]

  Miscarriage: Loss of the fetus without induction or instrumentation, also known as "spontaneous abortion." Vital pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan.

- Number of Participants With Ectopic Pregnancy Among Participants With Biochemical Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: From 2 weeks up to approximately 5-6 weeks after ET, within a treatment cycle] [Designated as safety issue: No]

  Ectopic pregnancy: A pregnancy in which the embryo attaches itself in a place other than inside the uterus. The most common site for an ectopic pregnancy is within one of the two fallopian tubes. Biochemical pregnancy: Pregnancy proven by a biochemical pregnancy test using urine samples or serum samples collected at least 14 days after ET. Participants not having a positive biochemical pregnancy test result, but

with an ultrasound scan showing at least one gestational sac were counted as having a biochemical pregnancy.

- Number of Participants With Ongoing Pregnancy in Any FTET Cycle [Time Frame: 10 weeks up to 9 months after ET within an FTET cycle] [Designated as safety issue: No]

  After the first and after the second treatment cycle (i.e., a cycle in which corifollitropin alfa was administered for ovarian stimulation), participants could continue with a maximum of three FTET cycles before starting the following treatment cycle. This measure summarizes the number of participants with ongoing pregnancy following ET within an FTET cycle. Ongoing pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan at least 10 weeks after ET, or confirmed by live birth.

- Cumulative Ongoing Pregnancy Rate: Percentage of Participants With Ongoing Pregnancy in Treatment Cycles 1, 2 or 3, or in Any FTET Cycle, or Who Had Ongoing Pregnancy That Was a Spontaneous Pregnancy [Time Frame: Up to approximately 26 months after first dose of corifollitropin alfa] [Designated as safety issue: No]

  The ongoing pregnancy rate, cumulative over the entire study (in percent), is defined as 100 times the number of participants who had an ongoing pregnancy in Treatment Cycles 1, 2 or 3, or in any FTET cycle, or who had a spontaneous ongoing pregnancy, divided by the total number of participants who were administered corifollitropin alfa in the study. A participant could only be represented once in the count of ongoing pregnancies for determination of cumulative ongoing pregnancy rate. After the first and after the second treatment cycle (i.e., a cycle in which corifollitropin alfa was administered for ovarian stimulation), participants could continue with a maximum of three FTET cycles before starting the following treatment cycle. A spontaneous pregnancy is a pregnancy that was not considered to have resulted from ET in a treatment cycle or FTET cycle.

- Serum Follicle Stimulating Hormone (FSH) Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1] [Designated as safety issue: No]

  Blood samples for assessment of serum FSH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum FSH Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2] [Designated as safety issue: No]

  Blood samples for assessment of serum FSH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum FSH Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3] [Designated as safety issue: No]

  Blood samples for assessment of serum FSH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Luteinizing Hormone (LH) Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1] [Designated as safety issue: No]

  Blood samples for assessment of serum LH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum LH Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2] [Designated as safety issue: No]

  Blood samples for assessment of serum LH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum LH Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3] [Designated as safety issue: No]

  Blood samples for assessment of serum LH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Estradiol Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1] [Designated as safety issue: No]

  Blood samples for assessment of serum estradiol were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Estradiol Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2] [Designated as safety issue: No]

Blood samples for assessment of serum estradiol were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Estradiol Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3] [Designated as safety issue: No]

  Blood samples for assessment of serum estradiol were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Progesterone Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1] [Designated as safety issue: No]

  Blood samples for assessment of serum progesterone were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Progesterone Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2] [Designated as safety issue: No]

  Blood samples for assessment of serum progesterone were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Progesterone Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3] [Designated as safety issue: No]

  Blood samples for assessment of serum progesterone were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Inhibin-B Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1] [Designated as safety issue: No]

  Blood samples for assessment of serum inhibin-B were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Inhibin-B Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2] [Designated as safety issue: No]

  Blood samples for assessment of serum inhibin-B were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

- Serum Inhibin-B Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3] [Designated as safety issue: No]

  Blood samples for assessment of serum inhibin-B were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

Enrollment:	682
Study Start Date:	September 2006
Study Completion Date:	May 2009
Primary Completion Date:	February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Corifollitropin alfa 150 µg Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of recombinant Human Chorion Gonadotropin ([rec]hCG) (5,000-10,000 IU/250 µg). Administration of (rec)hCG occurred when 3 follicles ≥17 mm were observed on ultrasound scan (USS). Daily dosing with Follicle Stimulating Hormone (FSH) (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone for luteal phase support was administered starting on the day of oocyte pick-up (34-36 hours after [rec]hCG) and continued for approximately 6 weeks. After COS cycles 1 and 2, Frozen-Thawed Embryo Transfer cycles (up to 3 after each COS cycle) could occur.	Drug: Corifollitropin alfa Corifollitropin alfa 150 µg administered as a single subcutaneous dose. Other Names:

	Org 36286 • SCH 900962 • MK-8962 Biological: FSH FSH administerd subcutaneously at a dose not to exceed 225 IU/day. Biological: GnRH antagonist GnRH antagonist administered subcutaneously at a dose of 0.25 mg/day. Biological: (rec)hCG (rec)hCG administered subcutaneously at a dose of 5,000-10,000 IU/250 µg. Drug: Progesterone Progesterone administered vaginally at a dose of at least 600 mg/day.

Detailed Description:

This trial is designed as an open-label, uncontrolled, repeated cycle trial to assess the non-immunogenicity and safety of corifollitropin alfa in participants undergoing repeated COS cycles for in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) using a multiple dose GnRH antagonist protocol. The trial period per participant will cover 1, 2 or 3 COS treatment cycles and no more than three (in-between two stimulation cycles) Frozen-Thawed Embryo Transfer (FTET) cycles following either or both of the first two treatment cycles. In each stimulation cycle, participants receive a single injection of corifollitropin alfa and one week later, treatment is continued with a daily dose of any FSH-containing preparation up to the day of (rec)hCG administration for final oocyte maturation. Assessment of anti-corifollitropin alfa antibodies and local tolerance after corifollitropin alfa injection are important safety endpoints in this trial.

Eligibility

Ages Eligible for Study:	18 Years to 39 Years
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Females of couples with an indication for COS and IVF or ICSI;
- >=18 and <=39 years of age at the time of signing informed consent;
- Body weight > 60 kg and body mass index (BMI) >=18 and <=29 kg/m^2;
- Normal menstrual cycle length: 24-35 days;

- Availability of ejaculatory sperm (use of donated and/or cryopreserved sperm is allowed);
- Willing and able to sign informed consent.

Exclusion Criteria:

- History of or any current (treated) endocrine abnormality;
- History of ovarian hyper-response or history of ovarian hyperstimulation syndrome (OHSS);
- History of or current polycystic ovary syndrome (PCOS);
- More than 20 basal antral follicles (size: <11 mm, both ovaries combined) as measured on USS in the early follicular phase (menstrual cycle day 2-5);
- Less than 2 ovaries or any other ovarian abnormality, including endometrioma >10 mm (visible on USS);
- Presence of unilateral or bilateral hydrosalpinx (visible on USS);
- More than three unsuccessful COS cycles since the last established ongoing pregnancy (if applicable);
- History of non- or low ovarian response to FSH/human menopausal gonadotrophin (hMG) treatment;
- FSH > 12 IU/L or luteinizing hormone (LH) > 12 IU/L as measured by the local laboratory (sample taken during the early follicular phase: menstrual cycle day 2-5);
- Any clinically relevant abnormal laboratory value based on a sample taken during the screening phase, including abnormal cervical smear (Papanicolaou [PAP]>=III, cervical intraepithelial neoplasia [CIN]>=1);
- Contraindications for the use of gonadotropins (e.g. tumors, pregnancy/lactation, undiagnosed vaginal bleeding, hypersensitivity, ovarian cysts) or GnRH antagonists (e.g. hypersensitivity, pregnancy/lactation);
- Recent history of or current epilepsy, human immunodeficiency virus (HIV) infection, thrombophilia, diabetes or cardiovascular, gastro-intestinal, hepatic, renal, or pulmonary disease;
- Abnormal karyotyping of the participant or her partner (if karyotyping is performed);
- History or presence of alcohol or drug abuse within 12 months prior to signing informed consent;
- Previous use of corifollitropin alfa;
- Use of hormonal preparations within 1 month prior to screening;
- Administration of investigational drugs within three months prior to signing informed consent.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696878

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Rombauts L, Lambalk CB, Schultze-Mosgau A, van Kuijk J, Verweij P, Gates D, Gordon K, Griesinger G. Intercycle variability of the ovarian response in patients undergoing repeated stimulation with corifollitropin alfa in a gonadotropin-releasing hormone antagonist protocol. Fertil Steril. 2015 Oct;104(4):884-890.e2. doi: 10.1016/j.fertnstert.2015.06.027. Epub 2015 Jul 15.

Norman RJ, Zegers-Hochschild F, Salle BS, Elbers J, Heijnen E, Marintcheva-Petrova M, Mannaerts B; Trust Investigators. Repeated ovarian stimulation with corifollitropin alfa in patients in a GnRH antagonist protocol: no concern for immunogenicity. Hum Reprod. 2011 Aug;26(8):2200-8. doi: 10.1093/humrep/der163. Epub 2011 May 27.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00696878 History of Changes
Other Study ID Numbers: P05714 MK-8962-007 38825 2004-004966-34

Study First Received:	June 11, 2008
Results First Received:	April 6, 2015
Last Updated:	May 20, 2015
Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Australia: Department of Health and Ageing Therapeutic Goods Administration Brazil: National Health Surveillance Agency Chile: Instituto de Salud Pública de Chile Denmark: Danish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: German Institute of Medical Documentation and Information Hungary: National Institute of Pharmacy Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Norway: Norwegian Medicines Agency Sweden: Medical Products Agency United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Infertility
Pharmacological effects of drugs
Hormones, Hormone Substitutes and Hormone Antagonists
Pharmacological Actions
Multi-center

Additional relevant MeSH terms:

Progesterone	Pharmacologic Actions
Hormones	Physiological Effects of Drugs
Hormones, Hormone Substitutes, and Hormone Antagonists	Progestins

ClinicalTrials.gov processed this record on May 08, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Corifollitropin Alfa in Participants Undergoing Repeated Controlled Ovarian Stimulation (COS) Cycles Using a Multiple Dose Gonadatropin Releasing Hormone (GnRH) Antagonist Protocol (Study 38825) (P05714) (Trust)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00696878

First received: June 11, 2008
Last updated: May 20, 2015
Last verified: May 2015
History of Changes

Results First Received: April 6, 2015

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	In Vitro Fertilization
Interventions:	Drug: Corifollitropin alfa Biological: FSH Biological: GnRH antagonist Biological: (rec)hCG Drug: Progesterone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
To complete study, a participant must have embryo transfer in the 3rd Controlled Ovarian Stimulation (COS) cycle (Treatment Cycle 3).

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of Gonadotropin Releasing Hormone (GnRH) antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of recombinant Human Chorion Gonadotropin ([rec]hCG) (5,000-10,000 IU/250 µg). Daily dosing with Follicle Stimulating Hormone (FSH) (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, Frozen-Thawed Embryo Transfer (FTET) cycles (up to 3 after each COS cycle) could occur.

Participant Flow: Overall Study

	Corifollitropin Alfa 150 µg
STARTED	**682**
COMPLETED	**178**
NOT COMPLETED	**504**
Adverse Event	**8**
Withdrawal by Subject	**87**
Stop Treat Cycle 3 not for Adverse Event	**18**
Pregnant prior to Treat Cycle 3	**304**
Trial stopped	**32**
Other reason (not specified)	**55**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Baseline Measures

	Corifollitropin Alfa 150 µg
Number of Participants [units: participants]	**682**

Age [units: years] Mean (Standard Deviation)	**32.9 (3.6)**
Gender [units: participants]	
Female	**682**
Male	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Clinically Relevant Immunogenicity [Time Frame: Pre-dose (Stimulation Day 1) and up to approximately 40 days post dose in each treatment cycle]

Measure Type	Primary
Measure Title	Percentage of Participants With Clinically Relevant Immunogenicity
Measure Description	Serum samples obtained pre-dose and at 2 weeks after embryo transfer (ET), or at cycle discontinuation and 2-3 weeks after cycle discontinuation if cycle was stopped before ET was performed, were analyzed for presence of anti-corifollitropin alfa antibodies using screening and confirmatory tests. If a participant was confirmed to have anti-corifollitropin alfa antibody present in a post dose sample according to these tests, review of adverse events (AEs) in the participant was performed. The sample was also tested to evaluate whether the antibody appeared to have neutralizing activity that would interfere with the study drug biological effect. A participant was determined to have clinically relevant immunogenicity if the participant had a confirmed post dose anti-corifollitropin alfa antibody test result accompanied by clinical signs of immunogenicity (e.g., hypersensitivity reaction), considering also the results of the test for neutralizing activity of any antibody present.
Time Frame	Pre-dose (Stimulation Day 1) and up to approximately 40 days post dose in each treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had a post dose sample for anti-corifollitropin alfa antibody testing

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Percentage of Participants With Clinically Relevant Immunogenicity	

[units: percentage of participants]	
Cycle 1 (n=681)	0.0
Cycle 2 (n=372)	0.0
Cycle 3 (n=192)	0.0

Statistical Analysis 1 for Percentage of Participants With Clinically Relevant Immunogenicity

Groups [1]	Corifollitropin Alfa 150 µg
Percentage with immunogenicity [2]	0.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	During sample size determination, the upper limit of the one-sided 95% confidence interval for the population incidence of immunogenicity, if no immunogenicity is observed, was calculated. If no immunogenicity is observed in the projected 150 participants who receive corifollitropin alfa during 3 COS cycles, then the upper limit for the population is 2%. For the projected 300 participants who receive corifollitropin alfa during 2 COS cycles, the upper limit for the population is 1%.
[2]	Other relevant estimation information:
	Provided limit is upper 1-sided 95% confidence limit for study population for percentage of participants with clinically relevant immunogenicity, after Cycle 1

Statistical Analysis 2 for Percentage of Participants With Clinically Relevant Immunogenicity

Groups [1]	Corifollitropin Alfa 150 µg
Percentage with immunogenicity [2]	0.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	During sample size determination, the upper limit of the one-sided 95% confidence interval for the population incidence of immunogenicity, if no immunogenicity is observed, was calculated. If no immunogenicity is observed in the projected 150 participants who receive corifollitropin alfa during 3 COS cycles, then the upper limit for the population is 2%. For the projected 300 participants who receive corifollitropin alfa during 2 COS cycles, the upper limit for the population is 1%.
[2]	Other relevant estimation information:
	Provided limit is upper 1-sided 95% confidence limit for study population for percentage of participants with clinically relevant immunogenicity, after Cycle 2

Statistical Analysis 3 for Percentage of Participants With Clinically Relevant Immunogenicity

Groups [1]	Corifollitropin Alfa 150 µg
Percentage with immunogenicity [2]	0.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	During sample size determination, the upper limit of the one-sided 95% confidence interval for the population incidence of immunogenicity, if no immunogenicity is observed, was calculated. If no immunogenicity is observed in the projected 150 participants who receive corifollitropin alfa during 3 COS cycles, then the upper limit for the population is 2%. For the projected 300 participants who receive corifollitropin alfa during 2 COS cycles, the upper limit for the population is 1%.
[2]	Other relevant estimation information:
	Provided limit is upper 1-sided 95% confidence limit for study population for percentage of participants with clinically relevant immunogenicity, after Cycle 3

2. Primary: Local Tolerance at Injection Site: Number of Participants With no Event of Itching and With Mild, Moderate and Severe Itching in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle]

Measure Type	Primary
Measure Title	Local Tolerance at Injection Site: Number of Participants With no Event of Itching and With Mild, Moderate and Severe Itching in Any of 3 Treatment Cycles
Measure Description	At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of itching. A participant with an event was counted once in this analysis.
Time Frame	30 minutes post dose in each treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Local Tolerance at Injection Site: Number of Participants With no Event of Itching and With Mild, Moderate and Severe Itching in Any of 3 Treatment Cycles [units: participants]	
None	**679**
Mild	**3**
Moderate	**0**
Severe	**0**

No statistical analysis provided for Local Tolerance at Injection Site: Number of Participants With no Event of Itching and With Mild, Moderate and Severe Itching in Any of 3 Treatment Cycles

3. Primary: Local Tolerance at Injection Site: Number of Participants With no Event of Pain and With Mild, Moderate and Severe Pain in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle]

Measure Type	Primary
Measure Title	Local Tolerance at Injection Site: Number of Participants With no Event of Pain and With Mild, Moderate and Severe Pain in Any of 3 Treatment Cycles
Measure Description	At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of pain. A participant with an event was counted once in this analysis.
Time Frame	30 minutes post dose in each treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Local Tolerance at Injection Site: Number of Participants With no Event of Pain and With Mild, Moderate and Severe Pain in Any of 3 Treatment Cycles [units: participants]	
None	**678**
Mild	**4**
Moderate	**0**
Severe	**0**

No statistical analysis provided for Local Tolerance at Injection Site: Number of Participants With no Event of Pain and With Mild, Moderate and Severe Pain in Any of 3 Treatment Cycles

4. Primary: Local Tolerance at Injection Site: Number of Participants With no Event of Redness and With Mild, Moderate and Severe Redness in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle]

Measure Type	Primary
Measure Title	Local Tolerance at Injection Site: Number of Participants With no Event of Redness and With Mild, Moderate and Severe Redness in Any of 3 Treatment Cycles
Measure Description	At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This

	measure reports results for the assessment of redness. A participant with an event was counted once in this analysis.
Time Frame	30 minutes post dose in each treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Local Tolerance at Injection Site: Number of Participants With no Event of Redness and With Mild, Moderate and Severe Redness in Any of 3 Treatment Cycles [units: participants]	
None	**654**
Mild	**28**
Moderate	**0**
Severe	**0**

No statistical analysis provided for Local Tolerance at Injection Site: Number of Participants With no Event of Redness and With Mild, Moderate and Severe Redness in Any of 3 Treatment Cycles

5. Primary: Local Tolerance at Injection Site: Number of Participants With no Event of Swelling and With Mild, Moderate and Severe Swelling in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle]

Measure Type	Primary
Measure Title	Local Tolerance at Injection Site: Number of Participants With no Event of Swelling and With Mild, Moderate and Severe Swelling in Any of 3 Treatment Cycles
Measure Description	At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results for the assessment of swelling. A participant with an event was counted once in this analysis.
Time Frame	30 minutes post dose in each treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Local Tolerance at Injection Site: Number of Participants With no Event of Swelling and With Mild, Moderate and Severe Swelling in Any of 3 Treatment Cycles [units: participants]	
None	**680**
Mild	**2**
Moderate	**0**
Severe	**0**

No statistical analysis provided for Local Tolerance at Injection Site: Number of Participants With no Event of Swelling and With Mild, Moderate and Severe Swelling in Any of 3 Treatment Cycles

6. Primary: Local Tolerance at Injection Site Overall Summary: Number of Participants With no Local Tolerance Event (Itching, Pain, Redness or Swelling) and With a Mild, Moderate and Severe Local Tolerance Event in Any of 3 Treatment Cycles [Time Frame: 30 minutes post dose in each treatment cycle]

Measure Type	Primary
Measure Title	Local Tolerance at Injection Site Overall Summary: Number of Participants With no Local Tolerance Event (Itching, Pain, Redness or Swelling) and With a Mild, Moderate and Severe Local Tolerance Event in Any of 3 Treatment Cycles
Measure Description	At 30 minutes after dosing in each treatment cycle, the corifollitropin alfa injection site was assessed for the presence of itching, pain, redness and swelling, each of which was scored as none (no event), mild, moderate or severe. This measure reports results considering the occurrence of any of the defined local tolerance events. A participant with an event was counted once in this analysis.
Time Frame	30 minutes post dose in each treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Local Tolerance at Injection Site Overall Summary: Number of Participants With no Local Tolerance Event (Itching, Pain, Redness or Swelling) and With a Mild, Moderate and Severe Local Tolerance Event in Any of 3 Treatment Cycles [units: participants]	
None	**647**
Mild	**35**
Moderate	**0**
Severe	**0**

No statistical analysis provided for Local Tolerance at Injection Site Overall Summary: Number of Participants With no Local Tolerance Event (Itching, Pain, Redness or Swelling) and With a Mild, Moderate and Severe Local Tolerance Event in Any of 3 Treatment Cycles

7. Primary: Number of Participants With AEs [Time Frame: Up to approximately 26 months after first dose of corifollitropin alfa]

Measure Type	Primary
Measure Title	Number of Participants With AEs
Measure Description	An AE was defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Time Frame	Up to approximately 26 months after first dose of corifollitropin alfa
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description

Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Number of Participants With AEs [units: participants]	**409**

No statistical analysis provided for Number of Participants With AEs

8. Primary: Number of Participants With Serious AEs (SAEs) [Time Frame: Up to approximately 26 months after first dose of corifollitropin alfa]

Measure Type	Primary
Measure Title	Number of Participants With Serious AEs (SAEs)
Measure Description	An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening, required in-patient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, or was a congenital anomaly/birth defect. SAEs that occurred in fetuses or infants during the study period are included in this summary of SAEs, and are allocated to the associated study participant who was administered corifollitropin alfa.
Time Frame	Up to approximately 26 months after first dose of corifollitropin alfa
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed	**682**

[units: participants]	
Number of Participants With Serious AEs (SAEs) **[units: participants]**	**51**

No statistical analysis provided for Number of Participants With Serious AEs (SAEs)

9. Primary: Number of Participants With Moderate to Severe Ovarian Hyperstimulation Syndrome (OHSS) [Time Frame: Up to approximately 1 month after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle]

Measure Type	Primary
Measure Title	Number of Participants With Moderate to Severe Ovarian Hyperstimulation Syndrome (OHSS)
Measure Description	OHSS was classified on study based on a slightly modified WHO Scientific Group (1973) classification: Grade I (mild) = characterized by excessive steroid secretion and ovarian enlargement (5-7 cm). Abdominal discomfort, including abdominal pain, is present. Grade II (moderate) = characterized by distinct ovarian cysts (ovary size 8-10 cm), accompanied by abdominal pain and tension, nausea, vomiting, diarrhea. Grade III (severe) = characterized by enlarged cystic ovaries (ovary size >10 cm), accompanied by ascites and occasionally hydrothorax. Abdominal tension and pain may be severe. Pronounced hydrothorax together with an abdominal cavity filled with cysts and fluid elevating the diaphragm may cause severe breathing difficulties. Large quantities of fluid inside the cysts and in the peritoneal and pleural cavities cause haemoconcentration and increased blood viscosity. In rare cases, the syndrome may further be complicated by the occurrence of thromboembolic phenomena.
Time Frame	Up to approximately 1 month after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed **[units: participants]**	**682**
Number of Participants With Moderate to Severe Ovarian Hyperstimulation Syndrome (OHSS) **[units: participants]**	
Cycle 1 (n=682)	**12**
Cycle 2 (n=375)	**4**

Cycle 3 (n=198)	**0**

No statistical analysis provided for Number of Participants With Moderate to Severe Ovarian Hyperstimulation Syndrome (OHSS)

10. Secondary: Amount of (Rec)FSH Needed From Stimulation Day 8 Onwards to Reach the Criterion for Administration of (Rec)hCG [Time Frame: Stimulation Day 8 to day of (rec)hCG administration (approximately Stimulation Day 10), within a treatment cycle]

Measure Type	Secondary
Measure Title	Amount of (Rec)FSH Needed From Stimulation Day 8 Onwards to Reach the Criterion for Administration of (Rec)hCG
Measure Description	Beginning on Stimulation Day 8 of each treatment cycle, (rec)FSH was administered daily until the criteria for administration of (rec)hCG (presence of 3 follicles ≥17 mm documented by ultrasonography) was reached. The total amount of (rec)FSH administered in each participant to reach the criteria for (rec)hCG administration was calculated.
Time Frame	Stimulation Day 8 to day of (rec)hCG administration (approximately Stimulation Day 10), within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**664**
Amount of (Rec)FSH Needed From Stimulation Day 8 Onwards to Reach the Criterion for Administration of (Rec)hCG [units: International Unit (IU)] Median (Full Range)	
Cycle 1 (n=658)	**400.0 (0 to 2100)**
Cycle 2 (n=364)	**450.0 (0 to 1950)**
Cycle 3 (n=190)	**450.0 (0 to 2250)**

No statistical analysis provided for Amount of (Rec)FSH Needed From Stimulation Day 8 Onwards to Reach the Criterion for Administration of (Rec)hCG

11. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 1 [Time Frame: Stimulation Day 1 in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 1
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 1 in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 1 in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**666**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 1 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**0.0 (0.1)**
follicles ≥15 mm	**0.0 (0.1)**
follicles ≥17 mm	**0.0 (0.1)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 1

12. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 2 [Time Frame: Stimulation Day 1 in Treatment Cycle 2]

Measure Type	Secondary

Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 2
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 1 in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 1 in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**370**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 2 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**0.0 (0.3)**
follicles ≥15 mm	**0.0 (0.0)**
follicles ≥17 mm	**0.0 (0.0)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 2

13. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 3 [Time Frame: Stimulation Day 1 in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 3
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 1 in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 1 in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**196**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 3 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**0.0 (0.2)**
follicles ≥15 mm	**0.0 (0.0)**
follicles ≥17 mm	**0.0 (0.0)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 1 During Treatment Cycle 3

14. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 1 [Time Frame: Stimulation Day 5 or 6 in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 1
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 5 or 6 in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 5 or 6 in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**677**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 1 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**5.1 (4.2)**
follicles ≥15 mm	**0.4 (1.0)**
follicles ≥17 mm	**0.1 (0.3)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 1

15. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 2 [Time Frame: Stimulation Day 5 or 6 in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 2
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 5 or 6 in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 5 or 6 in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on

	Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**372**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 2 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**4.8 (4.1)**
follicles ≥15 mm	**0.4 (1.0)**
follicles ≥17 mm	**0.1 (0.4)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 2

16. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 3 [Time Frame: Stimulation Day 5 or 6 in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 3
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 5 or 6 in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 5 or 6 in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg

Number of Participants Analyzed [units: participants]	**198**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 3 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**4.0 (3.3)**
follicles ≥15 mm	**0.3 (0.9)**
follicles ≥17 mm	**0.0 (0.3)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 5 or 6 During Treatment Cycle 3

17. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 1 [Time Frame: Stimulation Day 8 in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 1
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 8 in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 8 in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**660**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 1 [units: follicles] Mean (Standard Deviation)	

follicles ≥11 mm	**11.1 (5.9)**
follicles ≥15 mm	**3.7 (3.3)**
follicles ≥17 mm	**1.1 (1.8)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 1

18. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 2 [Time Frame: Stimulation Day 8 in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 2
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 8 in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 8 in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**363**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 2 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**10.7 (5.4)**
follicles ≥15 mm	**3.6 (3.3)**
follicles ≥17 mm	**1.2 (1.8)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 2

19. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 3 [Time Frame: Stimulation Day 8 in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 3
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on defined days during the treatment cycle was calculated.
Time Frame	Stimulation Day 8 in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had data for assessment of follicles ≥11 mm on Stimulation Day 8 in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**194**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 3 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**10.0 (5.8)**
follicles ≥15 mm	**3.4 (3.3)**
follicles ≥17 mm	**1.1 (1.8)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Stimulation Day 8 During Treatment Cycle 3

20. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 1 [Time Frame: Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 1
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on the day of (rec)hCG administration during the treatment cycle was recorded.
Time Frame	Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG, and had data for assessment of follicles ≥11 mm on day of (rec)hCG administration in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**640**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 1 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**14.5 (6.4)**
follicles ≥15 mm	**9.2 (4.3)**
follicles ≥17 mm	**5.4 (2.8)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 1

21. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 2 [Time Frame: Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 2
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on the day

	of (rec)hCG administration during the treatment cycle was recorded.
Time Frame	Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG, and had data for assessment of follicles ≥11 mm on day of (rec)hCG administration in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**359**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 2 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**13.9 (6.0)**
follicles ≥15 mm	**9.0 (3.9)**
follicles ≥17 mm	**5.4 (2.7)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 2

22. Secondary: Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 3 [Time Frame: Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 3
Measure Description	For each participant, the number of follicles ≥11 mm, ≥15 mm and ≥17 mm documented by ultrasonography on the day of (rec)hCG administration during the treatment cycle was recorded.
Time Frame	Day of (rec)hCG administration (approximately Stimulation Day 10) in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG, and had data for assessment of follicles ≥11 mm on day of (rec)hCG administration in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**185**
Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 3 [units: follicles] Mean (Standard Deviation)	
follicles ≥11 mm	**13.7 (6.4)**
follicles ≥15 mm	**9.0 (4.7)**
follicles ≥17 mm	**5.4 (2.9)**

No statistical analysis provided for Number of Follicles ≥11 mm, ≥15 mm and ≥17 mm Documented by Ultrasonography Performed in the Participant on Day of (Rec)hCG Administration During Treatment Cycle 3

23. Secondary: Number of Oocytes Retrieved in a Participant Among Entire Study Population [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Oocytes Retrieved in a Participant Among Entire Study Population
Measure Description	Oocyte retrieval, also known as oocyte pick-up, is a technique used in in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) in order to remove oocytes from the ovary of the female, enabling fertilization outside the body. The number of oocytes retrieved, per participant, is summarized.
Time Frame	Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Number of Oocytes Retrieved in a Participant Among Entire Study Population [units: number of oocytes] Mean (Standard Deviation)	
Cycle 1 (n=682)	**11.9 (7.2)**
Cycle 2 (n=375)	**11.5 (6.8)**
Cycle 3 (n=198)	**11.3 (7.6)**

No statistical analysis provided for Number of Oocytes Retrieved in a Participant Among Entire Study Population

24. Secondary: Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 1 [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 1
Measure Description	This measure summarizes results of assessment of the quality of oocytes performed following oocyte retrieval, among participants scheduled for ICSI in Treatment Cycle 1. For oocytes obtained from each participant, the number in each of 3 stages of oocyte development were determined. The earliest phase is the germinal vesicles stage, during which the immature oocyte appears as a large vesicular nucleus. Metaphase I is an intermediate stage during which the vesicles have broken down and the polar body has not yet formed; the oocyte is still immature. Metaphase II is the mature oocyte and is indicated by the presence of the polar body. Rating of quality for usefulness in ICSI follows the order metaphase II (best quality), metaphase I (lesser quality) and germinal vesicles stage (poorest quality). Only metaphase II oocytes can be fertilized. Metaphase I oocytes can develop in vitro to metaphase II oocytes. Germinal vesicles stage oocytes are the least useful for ICSI procedures.
Time Frame	Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and were to have ICSI in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**462**
Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 1 [units: number of oocytes] Mean (Standard Deviation)	
Oocytes assessed	**12.2 (7.0)**
Metaphase I	**0.8 (1.4)**
Metaphase II	**9.8 (6.0)**
Germinal vesicles stage	**0.9 (1.4)**

No statistical analysis provided for Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 1

25. Secondary: Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 2 [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 2
Measure Description	This measure summarizes results of assessment of the quality of oocytes performed following oocyte retrieval, among participants scheduled for ICSI in Treatment Cycle 2. For oocytes obtained from each participant, the number in each of 3 stages of oocyte development were determined. The earliest phase is the germinal vesicles stage, during which the immature oocyte appears as a large vesicular nucleus. Metaphase I is an intermediate stage during which the vesicles have broken down and the polar body has not yet formed; the oocyte is still immature. Metaphase II is the mature oocyte and is indicated by the presence of the polar body. Rating of quality for usefulness in ICSI follows the order metaphase II (best quality), metaphase I (lesser quality) and germinal vesicles stage (poorest quality). Only metaphase II oocytes can be fertilized. Metaphase I oocytes can develop in vitro to metaphase II oocytes. Germinal vesicles stage oocytes are the least useful for ICSI procedures.
Time Frame	Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and were to have ICSI in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**281**
Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 2 [units: number of oocytes] Mean (Standard Deviation)	
Oocytes assessed	**11.6 (6.5)**
Metaphase I	**0.9 (1.5)**
Metaphase II	**9.3 (5.4)**
Germinal vesicles stage	**0.8 (1.4)**

No statistical analysis provided for Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 2

26. Secondary: Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 3 [Time Frame: Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 3
Measure Description	This measure summarizes results of assessment of the quality of oocytes performed following oocyte retrieval, among participants scheduled for ICSI in Treatment Cycle 3. For oocytes obtained from each participant, the number in each of 3 stages of oocyte development were determined. The earliest phase is the germinal vesicles stage, during which the immature oocyte appears as a large vesicular nucleus. Metaphase I is an intermediate stage during which the vesicles have broken down and the polar body has not yet formed; the oocyte is still immature. Metaphase II is the mature oocyte and is indicated by the presence of the polar body. Rating of quality for usefulness in ICSI follows the order metaphase II (best quality), metaphase I (lesser quality) and germinal vesicles stage (poorest quality). Only metaphase II oocytes can be fertilized. Metaphase I oocytes can develop in vitro to metaphase II oocytes. Germinal vesicles stage oocytes are the least useful for ICSI procedures.
Time Frame	Day of oocyte pick-up, 34-36 hours after (rec)hCG administration (approximately Stimulation Day 10), in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and were to have ICSI in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**151**
Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 3 [units: number of oocytes] Mean (Standard Deviation)	
Oocytes assessed	**11.3 (6.3)**
Metaphase I	**0.8 (1.3)**
Metaphase II	**9.1 (5.2)**
Germinal vesicles stage	**0.9 (1.5)**

No statistical analysis provided for Quality of Oocytes Assessed Prior to Planned ICSI in Treatment Cycle 3

27. Secondary: Number of Fertilized Oocytes Obtained in Treatment Cycle 1 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained in Treatment Cycle 1
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure, by category of number of pronuclei (PN) present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on

	Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**649**
Number of Fertilized Oocytes Obtained in Treatment Cycle 1 [units: number of fertilized oocytes] Mean (Standard Deviation)	
0 PN fertilized oocytes	**2.2 (2.9)**
1 PN fertilized oocytes	**0.2 (0.6)**
2 PN fertilized oocytes	**6.1 (4.0)**
≥3 PN fertilized oocytes	**0.3 (0.7)**
Other fertilized oocytes	**0.7 (1.6)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained in Treatment Cycle 1

28. Secondary: Number of Fertilized Oocytes Obtained in Treatment Cycle 2 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained in Treatment Cycle 2
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**359**
Number of Fertilized Oocytes Obtained in Treatment Cycle 2 [units: number of fertilized oocytes] Mean (Standard Deviation)	
0 PN fertilized oocytes	**2.1 (2.5)**
1 PN fertilized oocytes	**0.3 (0.9)**
2 PN fertilized oocytes	**6.1 (4.0)**
≥3 PN fertilized oocytes	**0.3 (0.7)**
Other fertilized oocytes	**0.6 (1.2)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained in Treatment Cycle 2

29. Secondary: Number of Fertilized Oocytes Obtained in Treatment Cycle 3 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained in Treatment Cycle 3
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**188**

Number of Fertilized Oocytes Obtained in Treatment Cycle 3 **[units: number of fertilized oocytes]** **Mean (Standard Deviation)**	
0 PN fertilized oocytes	**1.8 (2.3)**
1 PN fertilized oocytes	**0.2 (0.5)**
2 PN fertilized oocytes	**6.2 (4.2)**
≥3 PN fertilized oocytes	**0.3 (0.7)**
Other fertilized oocytes	**0.8 (1.6)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained in Treatment Cycle 3

30. Secondary: Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 1 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 1
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ICSI procedure that were cryopreserved (frozen) for possible later use, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 1, and were enrolled at a site using cyropreservation at the fertilized oocyte level

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed **[units: participants]**	**103**
Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 1	

[units: number of fertilized oocytes] Mean (Standard Deviation)	
0 PN fertilized oocytes	0.0 (0.0)
1 PN fertilized oocytes	0.0 (0.1)
2 PN fertilized oocytes	1.9 (3.2)
≥3 PN fertilized oocytes	0.0 (0.0)
Other fertilized oocytes	0.0 (0.0)

No statistical analysis provided for Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 1

31. Secondary: Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 2 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 2
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ICSI procedure that were cryopreserved (frozen) for possible later use, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 2, and were enrolled at a site using cyropreservation at the fertilized oocyte level

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**55**
Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 2 [units: number of fertilized oocytes] Mean (Standard Deviation)	

0 PN fertilized oocytes	**0.0 (0.0)**
1 PN fertilized oocytes	**0.0 (0.0)**
2 PN fertilized oocytes	**1.6 (3.3)**
≥3 PN fertilized oocytes	**0.0 (0.0)**
Other fertilized oocytes	**0.0 (0.0)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 2

32. Secondary: Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 3 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 3
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ICSI procedure that were cryopreserved (frozen) for possible later use, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 3, and were enrolled at a site using cyropreservation at the fertilized oocyte level

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**32**
Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 3 **[units: number of fertilized oocytes]** **Mean (Standard Deviation)**	
0 PN fertilized oocytes	**0.0 (0.0)**

1 PN fertilized oocytes	**0.0 (0.0)**
2 PN fertilized oocytes	**1.1 (2.1)**
≥3 PN fertilized oocytes	**0.0 (0.0)**
Other fertilized oocytes	**0.0 (0.0)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained That Were Frozen in Treatment Cycle 3

33. Secondary: Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 1 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 1
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure that were used for embryo development, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**649**
Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 1 **[units: number of fertilized oocytes]** **Mean (Standard Deviation)**	
0 PN fertilized oocytes	**0.6 (1.9)**
1 PN fertilized oocytes	**0.1 (0.3)**
2 PN fertilized oocytes	**5.7 (4.1)**

≥3 PN fertilized oocytes	**0.0 (0.0)**
Other fertilized oocytes	**0.0 (0.1)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 1

34. Secondary: Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 2 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 2
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure that were used for embryo development, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**359**
Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 2 **[units: number of fertilized oocytes]** **Mean (Standard Deviation)**	
0 PN fertilized oocytes	**0.6 (1.8)**
1 PN fertilized oocytes	**0.1 (0.8)**
2 PN fertilized oocytes	**5.8 (3.9)**
≥3 PN fertilized oocytes	**0.0 (0.0)**
Other fertilized oocytes	**0.0 (0.2)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 2

35. Secondary: Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 3 [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 3
Measure Description	This measure presents the number of fertilized oocytes obtained per participant from the IVF or ISCI procedure that were used for embryo development, by category of number of PN present: 0 PN, 1 PN, 2 PN, ≥3 PN, other (fertilized oocyte that was not placed in PN category). Normal fertilized ooctyes have 2 pronuclei (2 PN).
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**188**
Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 3 **[units: number of fertilized oocytes]** **Mean (Standard Deviation)**	
0 PN fertilized oocytes	**0.5 (1.6)**
1 PN fertilized oocytes	**0.1 (0.4)**
2 PN fertilized oocytes	**6.0 (4.2)**
≥3 PN fertilized oocytes	**0.0 (0.1)**
Other fertilized oocytes	**0.1 (0.6)**

No statistical analysis provided for Number of Fertilized Oocytes Obtained That Were Used for Embryo Development in Treatment Cycle 3

36. Secondary: Fertilization Rate [Time Frame: 16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle]

Measure Type	Secondary
Measure Title	Fertilization Rate
Measure Description	The fertilization rate (in percent) is defined as 100 times the ratio of the number of fertilized 2 PN oocytes obtained and the number of oocytes that was used for fertilization, per participant.
Time Frame	16-18 hours after start of IVF or ICSI, which occurs on day of oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**659**
Fertilization Rate [units: percentage of oocytes] Mean (Standard Deviation)	
Cycle 1 (n=649)	**67.0 (26.6)**
Cycle 2 (n=359)	**66.0 (25.8)**
Cycle 3 (n=188)	**67.3 (23.4)**

No statistical analysis provided for Fertilization Rate

37. Secondary: Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 1 [Time Frame: Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 1
Measure Description	At Day 3 after oocyte pick-up, embryos obtained from IVF or ISCI process for each participant were counted and quality

	was assessed. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."
Time Frame	Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 1 and had embryo assessment at Day 3 after oocyte pick-up; excludes participants with embryo transfer or embryos cryopreserved before Day 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**610**
Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 1 **[units: number of embryos]** **Mean (Standard Deviation)**	
Total obtained	**6.4 (4.5)**
Good quality (Grade 1 + 2)	**3.2 (3.1)**
Grade 1	**1.2 (2.1)**
Grade 2	**1.9 (2.3)**
Grade 3	**2.3 (2.5)**
Other grade	**1.0 (2.1)**

No statistical analysis provided for Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 1

38. Secondary: Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 2 [Time Frame: Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 2
Measure Description	At Day 3 after oocyte pick-up, embryos obtained from IVF or ISCI process for each participant were counted and quality was assessed. Quality was rated as Grade 1, 2 or 3, or "other grade", with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of "good quality."

Time Frame	Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 2 and had embryo assessment at Day 3 after oocyte pick-up; excludes participants with embryo transfer or embryos cryopreserved before Day 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**351**
Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 2 **[units: number of embryos]** **Mean (Standard Deviation)**	
Total obtained	**6.5 (4.4)**
Good quality (Grade 1 + 2)	**2.9 (2.8)**
Grade 1	**1.2 (1.9)**
Grade 2	**1.8 (2.0)**
Grade 3	**2.4 (2.7)**
Other grade	**1.2 (2.4)**

No statistical analysis provided for Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 2

39. Secondary: Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 3 [Time Frame: Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 3
Measure Description	At Day 3 after oocyte pick-up, embryos obtained from IVF or ISCI process for each participant were counted and quality was assessed. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	Day 3 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment

	Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had IVF and/or ICSI in Treatment Cycle 3 and had embryo assessment at Day 3 after oocyte pick-up; excludes participants with embryo transfer or embryos cryopreserved before Day 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**186**
Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 3 **[units: number of embryos]** **Mean (Standard Deviation)**	
Total obtained	**6.6 (4.8)**
Good quality (Grade 1 + 2)	**2.8 (2.7)**
Grade 1	**1.0 (1.9)**
Grade 2	**1.8 (2.0)**
Grade 3	**2.6 (3.0)**
Other grade	**1.1 (2.2)**

No statistical analysis provided for Number and Quality of Embryos Obtained at Day 3 After Oocyte Pick-up in Treatment Cycle 3

40. Secondary: Number of Embryos Transferred [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Embryos Transferred
Measure Description	ET is the procedure in which one or more embryos are placed in the uterus. The number of embryos transferred, per participant, is summarized.
Time Frame	At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ET

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**642**
Number of Embryos Transferred [units: number of embryos] Mean (Standard Deviation)	
Cycle 1 (n=616)	**1.9 (0.7)**
Cycle 2 (n=340)	**2.1 (0.7)**
Cycle 3 (n=178)	**2.2 (0.7)**

No statistical analysis provided for Number of Embryos Transferred

41. Secondary: Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 1 [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 1
Measure Description	The number of embryos transferred, for each participant, by category of number of “good quality” embryos transferred, is summarized. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ET in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**616**
Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 1 [units: participants]	
With 0 good quality embryos transferred	**110**
With 1 good quality embryo transferred	**230**
With 2 good quality embryos transferred	**201**
With 3 good quality embryos transferred	**75**

No statistical analysis provided for Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 1

42. Secondary: Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 2 [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 2
Measure Description	The number of embryos transferred, for each participant, by category of number of “good quality” embryos transferred, is summarized. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ET in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1).

	Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**340**
Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 2 [units: participants]	
With 0 good quality embryos transferred	**81**
With 1 good quality embryo transferred	**80**
With 2 good quality embryos transferred	**122**
With 3 good quality embryos transferred	**57**

No statistical analysis provided for Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 2

43. Secondary: Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 3 [Time Frame: At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 3
Measure Description	The number of embryos transferred, for each participant, by category of number of “good quality” embryos transferred, is summarized. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	At ET, Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ET in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**178**
Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 3 [units: participants]	
With 0 good quality embryos transferred	**31**
With 1 good quality embryo transferred	**49**
With 2 good quality embryos transferred	**65**
With 3 good quality embryos transferred	**33**

No statistical analysis provided for Number of Participants by Category of Number of Good Quality Embryos Transferred in Treatment Cycle 3

44. Secondary: Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 1 [Time Frame: Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 1
Measure Description	The number of embryos that were cryopreserved (frozen) for possible later use, for each participant, overall and by embryo quality categories, is summarized. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**

Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 1 [units: number of embryos] Mean (Standard Deviation)	
Total frozen	1.6 (2.7)
Good quality (Grade 1 + 2)	1.2 (2.3)
Grade 1	0.4 (1.2)
Grade 2	0.8 (1.7)
Grade 3	0.4 (1.0)
Other grade	0.1 (0.4)

No statistical analysis provided for Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 1

45. Secondary: Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 2 [Time Frame: Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 2
Measure Description	The number of embryos that were cryopreserved (frozen) for possible later use, for each participant, overall and by embryo quality categories, is summarized. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	375
Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 2	

[units: number of embryos] Mean (Standard Deviation)	
Total frozen	1.1 (2.1)
Good quality (Grade 1 + 2)	0.8 (1.7)
Grade 1	0.3 (1.0)
Grade 2	0.5 (1.3)
Grade 3	0.3 (0.9)
Other grade	0.0 (0.4)

No statistical analysis provided for Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 2

46. Secondary: Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 3 [Time Frame: Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 3
Measure Description	The number of embryos that were cryopreserved (frozen) for possible later use, for each participant, overall and by embryo quality categories, is summarized. Quality was rated as Grade 1, 2 or 3, or “other grade”, with Grade 1 representing the best quality. The 2 highest quality grades (Grade 1 + 2) were combined into a summary category of “good quality.”
Time Frame	Day 3 or Day 5 after oocyte pick-up (34-36 hours after [rec]hCG administration [approximately Stimulation Day 10]), in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	198
Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 3 [units: number of embryos]	

Mean (Standard Deviation)	
Total frozen	1.1 (2.2)
Good quality (Grade 1 + 2)	0.8 (1.7)
Grade 1	0.3 (1.1)
Grade 2	0.5 (1.3)
Grade 3	0.3 (1.0)
Other grade	0.0 (0.4)

No statistical analysis provided for Number and Quality of Embryos Obtained That Were Frozen in Treatment Cycle 3

47. Secondary: Implantation Rate for Participants With ET [Time Frame: Approximately 5-6 weeks after ET, within a treatment cycle]

Measure Type	Secondary
Measure Title	Implantation Rate for Participants With ET
Measure Description	The implantation rate (in percent) is defined as 100 times the maximum number of gestational sacs as assessed by any ultrasound scan after ET divided by the number of embryos transferred per participant.
Time Frame	Approximately 5-6 weeks after ET, within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ET

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	642
Implantation Rate for Participants With ET [units: percentage of embryos] Mean (Standard Deviation)	
Cycle 1 (n=616)	21.2 (36.2)
Cycle 2 (n=340)	16.6 (31.0)
Cycle 3 (n=178)	16.3 (30.0)

No statistical analysis provided for Implantation Rate for Participants With ET

48. Secondary: Number of Participants With Biochemical Pregnancy, Clinical Pregnancy, Vital Pregnancy and Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: ≥14 days (for biochemical pregnancy), 5-6 weeks (for clinical pregnancy), 5-6 weeks to 10 weeks (for vital pregnancy) and 10 weeks up to 9 months (for ongoing pregnancy) after ET, within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Participants With Biochemical Pregnancy, Clinical Pregnancy, Vital Pregnancy and Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3
Measure Description	Biochemical pregnancy: Pregnancy proven by a biochemical pregnancy test using urine samples or serum samples collected at least 14 days after ET. Participants not having a positive biochemical pregnancy test result, but with an ultrasound scan showing at least one gestational sac were counted as having a biochemical pregnancy. Clinical pregnancy: Presence of at least one gestational sac as assessed by ultrasound scan. Vital pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan. Ongoing pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan at least 10 weeks after ET, or confirmed by live birth.
Time Frame	≥14 days (for biochemical pregnancy), 5-6 weeks (for clinical pregnancy), 5-6 weeks to 10 weeks (for vital pregnancy) and 10 weeks up to 9 months (for ongoing pregnancy) after ET, within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Number of Participants With Biochemical Pregnancy, Clinical Pregnancy, Vital Pregnancy and Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3 [units: participants]	
Biochemical pregnancy	**340**
Clinical pregnancy	**303**
Vital pregnancy	**278**
Ongoing pregnancy	**272**

No statistical analysis provided for Number of Participants With Biochemical Pregnancy, Clinical Pregnancy, Vital Pregnancy and Ongoing

Pregnancy in Any of Treatment Cycles 1, 2 or 3

49. Secondary: Number of Participants With Singleton and Multiple Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: 10 weeks up to 9 months after ET, within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Participants With Singleton and Multiple Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3
Measure Description	Singleton pregnancy is a pregnancy in which one fetus develops in the uterus. Multiple pregnancy is a pregnancy in which more than one fetus develops simultaneously in the uterus. Ongoing pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan at least 10 weeks after ET, or confirmed by live birth.
Time Frame	10 weeks up to 9 months after ET, within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ongoing pregnancy in any of Treatment Cycles 1, 2 or 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**272**
Number of Participants With Singleton and Multiple Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3 [units: participants]	
Singleton ongoing pregnancy	**226**
Multiple ongoing pregnancy	**46**

No statistical analysis provided for Number of Participants With Singleton and Multiple Ongoing Pregnancy in Any of Treatment Cycles 1, 2 or 3

50. Secondary: Number of Participants With Miscarriage Among Participants With Clinical Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: 5-6 weeks up to 9 months after ET, within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Participants With Miscarriage Among Participants With Clinical Pregnancy in Any of Treatment Cycles 1, 2 or 3

Measure Description	Miscarriage: Loss of the fetus without induction or instrumentation, also known as “spontaneous abortion.” Clinical pregnancy: Presence of at least one gestational sac as assessed by ultrasound scan.
Time Frame	5-6 weeks up to 9 months after ET, within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had clinical pregnancy in any of Treatment Cycles 1, 2 or 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**303**
Number of Participants With Miscarriage Among Participants With Clinical Pregnancy in Any of Treatment Cycles 1, 2 or 3 [units: participants]	**37**

No statistical analysis provided for Number of Participants With Miscarriage Among Participants With Clinical Pregnancy in Any of Treatment Cycles 1, 2 or 3

51. Secondary: Number of Participants With Miscarriage Among Participants With Vital Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: 5-6 weeks up to 9 months after ET, within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Participants With Miscarriage Among Participants With Vital Pregnancy in Any of Treatment Cycles 1, 2 or 3
Measure Description	Miscarriage: Loss of the fetus without induction or instrumentation, also known as “spontaneous abortion.” Vital pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan.
Time Frame	5-6 weeks up to 9 months after ET, within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had vital pregnancy in any of Treatment Cycles 1, 2 or 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**278**
Number of Participants With Miscarriage Among Participants With Vital Pregnancy in Any of Treatment Cycles 1, 2 or 3 [units: participants]	**5**

No statistical analysis provided for Number of Participants With Miscarriage Among Participants With Vital Pregnancy in Any of Treatment Cycles 1, 2 or 3

52. Secondary: Number of Participants With Ectopic Pregnancy Among Participants With Biochemical Pregnancy in Any of Treatment Cycles 1, 2 or 3 [Time Frame: From 2 weeks up to approximately 5-6 weeks after ET, within a treatment cycle]

Measure Type	Secondary
Measure Title	Number of Participants With Ectopic Pregnancy Among Participants With Biochemical Pregnancy in Any of Treatment Cycles 1, 2 or 3
Measure Description	Ectopic pregnancy: A pregnancy in which the embryo attaches itself in a place other than inside the uterus. The most common site for an ectopic pregnancy is within one of the two fallopian tubes. Biochemical pregnancy: Pregnancy proven by a biochemical pregnancy test using urine samples or serum samples collected at least 14 days after ET. Participants not having a positive biochemical pregnancy test result, but with an ultrasound scan showing at least one gestational sac were counted as having a biochemical pregnancy.
Time Frame	From 2 weeks up to approximately 5-6 weeks after ET, within a treatment cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had biochemical pregnancy in any of Treatment Cycles 1, 2 or 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**340**
Number of Participants With Ectopic Pregnancy Among Participants With Biochemical Pregnancy in Any of Treatment Cycles 1, 2 or 3 [units: participants]	**9**

No statistical analysis provided for Number of Participants With Ectopic Pregnancy Among Participants With Biochemical Pregnancy in Any of Treatment Cycles 1, 2 or 3

53. Secondary: Number of Participants With Ongoing Pregnancy in Any FTET Cycle [Time Frame: 10 weeks up to 9 months after ET within an FTET cycle]

Measure Type	Secondary
Measure Title	Number of Participants With Ongoing Pregnancy in Any FTET Cycle
Measure Description	After the first and after the second treatment cycle (i.e., a cycle in which corifollitropin alfa was administered for ovarian stimulation), participants could continue with a maximum of three FTET cycles before starting the following treatment cycle. This measure summarizes the number of participants with ongoing pregnancy following ET within an FTET cycle. Ongoing pregnancy: Presence of at least one fetus with heart activity as assessed by ultrasound scan at least 10 weeks after ET, or confirmed by live birth.
Time Frame	10 weeks up to 9 months after ET within an FTET cycle
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and had ET in any FTET cycle

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**209**
Number of Participants With Ongoing Pregnancy in Any FTET Cycle [units: participants]	**48**

No statistical analysis provided for Number of Participants With Ongoing Pregnancy in Any FTET Cycle

54. Secondary: Cumulative Ongoing Pregnancy Rate: Percentage of Participants With Ongoing Pregnancy in Treatment Cycles 1, 2 or 3, or in Any FTET Cycle, or Who Had Ongoing Pregnancy That Was a Spontaneous Pregnancy [Time Frame: Up to approximately 26 months after first dose of corifollitropin alfa]

Measure Type	Secondary
Measure Title	Cumulative Ongoing Pregnancy Rate: Percentage of Participants With Ongoing Pregnancy in Treatment Cycles 1, 2 or 3, or in Any FTET Cycle, or Who Had Ongoing Pregnancy That Was a Spontaneous Pregnancy
Measure Description	The ongoing pregnancy rate, cumulative over the entire study (in percent), is defined as 100 times the number of participants who had an ongoing pregnancy in Treatment Cycles 1, 2 or 3, or in any FTET cycle, or who had a spontaneous ongoing pregnancy, divided by the total number of participants who were administered corifollitropin alfa in the study. A participant could only be represented once in the count of ongoing pregnancies for determination of cumulative ongoing pregnancy rate. After the first and after the second treatment cycle (i.e., a cycle in which corifollitropin alfa was administered for ovarian stimulation), participants could continue with a maximum of three FTET cycles before starting the following treatment cycle. A spontaneous pregnancy is a pregnancy that was not considered to have resulted from ET in a treatment cycle or FTET cycle.
Time Frame	Up to approximately 26 months after first dose of corifollitropin alfa
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**682**
Cumulative Ongoing Pregnancy Rate: Percentage of Participants With Ongoing Pregnancy in Treatment Cycles 1, 2 or 3, or in Any FTET Cycle, or Who Had Ongoing Pregnancy That Was a Spontaneous Pregnancy [units: percentage of participants]	**50.6**

No statistical analysis provided for Cumulative Ongoing Pregnancy Rate: Percentage of Participants With Ongoing Pregnancy in Treatment Cycles 1, 2 or 3, or in Any FTET Cycle, or Who Had Ongoing Pregnancy That Was a Spontaneous Pregnancy

55. Secondary: Serum Follicle Stimulating Hormone (FSH) Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Serum Follicle Stimulating Hormone (FSH) Levels in Treatment Cycle 1
Measure Description	Blood samples for assessment of serum FSH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**658**
Serum Follicle Stimulating Hormone (FSH) Levels in Treatment Cycle 1 **[units: International Units (IU)/L]** **Mean (Standard Deviation)**	
Stimulation Day 1 (pre-dose) (n=651)	**7.18 (2.34)**
Stimulation Day 5 or 6 (n=648)	**24.00 (6.36)**
Stimulation Day 8 (n=634)	**13.23 (3.40)**
Day of (rec)hCG injection (n=643)	**13.63 (3.69)**
Day of embryo transfer (n=593)	**3.21 (1.68)**
2 weeks after embryo transfer (n=611)	**4.84 (3.51)**

No statistical analysis provided for Serum Follicle Stimulating Hormone (FSH) Levels in Treatment Cycle 1

56. Secondary: Serum FSH Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Serum FSH Levels in Treatment Cycle 2
Measure Description	

	Blood samples for assessment of serum FSH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**364**
Serum FSH Levels in Treatment Cycle 2 **[units: IU/L]** **Mean (Standard Deviation)**	
Stimulation Day 1 (pre-dose) (n=357)	**7.17 (2.17)**
Stimulation Day 5 or 6 (n=358)	**24.24 (5.75)**
Stimulation Day 8 (n=346)	**13.38 (3.35)**
Day of (rec)hCG injection (n=358)	**13.78 (3.74)**
Day of embryo transfer (n=326)	**3.20 (1.45)**
2 weeks after embryo transfer (n=333)	**5.07 (3.33)**

No statistical analysis provided for Serum FSH Levels in Treatment Cycle 2

57. Secondary: Serum FSH Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Serum FSH Levels in Treatment Cycle 3
Measure Description	Blood samples for assessment of serum FSH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.

Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**190**
Serum FSH Levels in Treatment Cycle 3 **[units: IU/L]** **Mean (Standard Deviation)**	
Stimulation Day 1 (pre-dose) (n=185)	**7.50 (5.24)**
Stimulation Day 5 or 6 (n=186)	**24.51 (5.93)**
Stimulation Day 8 (n=184)	**13.56 (3.35)**
Day of (rec)hCG injection (n=183)	**13.62 (3.49)**
Day of embryo transfer (n=168)	**3.17 (1.55)**
2 weeks after embryo transfer (n=173)	**5.01 (3.40)**

No statistical analysis provided for Serum FSH Levels in Treatment Cycle 3

58. Secondary: Serum Luteinizing Hormone (LH) Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Serum Luteinizing Hormone (LH) Levels in Treatment Cycle 1
Measure Description	Blood samples for assessment of serum LH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**658**
Serum Luteinizing Hormone (LH) Levels in Treatment Cycle 1 [units: IU/L] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=651)	**5.07 (1.86)**
Stimulation Day 5 or 6 (n=648)	**4.86 (5.39)**
Stimulation Day 8 (n=634)	**1.34 (1.55)**
Day of (rec)hCG injection (n=643)	**1.53 (1.98)**
Day of embryo transfer (n=593)	**NA [1]**
2 weeks after embryo transfer (n=611)	**3.27 (2.57)**

[1] If more than 1/3 of the values per assessment day were smaller than the lower limit of quantitation (LLOQ) of the analytical method (0.6 IU/L), mean and SD are reported as missing.

No statistical analysis provided for Serum Luteinizing Hormone (LH) Levels in Treatment Cycle 1

59. Secondary: Serum LH Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Serum LH Levels in Treatment Cycle 2
Measure Description	Blood samples for assessment of serum LH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**364**
Serum LH Levels in Treatment Cycle 2 [units: IU/L] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=357)	**5.13 (1.86)**
Stimulation Day 5 or 6 (n=358)	**4.78 (5.18)**
Stimulation Day 8 (n=346)	**1.35 (1.77)**
Day of (rec)hCG injection (n=358)	**1.67 (2.15)**
Day of embryo transfer (n=326)	**NA** [1]
2 weeks after embryo transfer (n=333)	**3.41 (2.48)**

[1] If more than 1/3 of the values per assessment day were smaller than the LLOQ of the analytical method (0.6 IU/L), mean and SD are reported as missing.

No statistical analysis provided for Serum LH Levels in Treatment Cycle 2

60. Secondary: Serum LH Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Serum LH Levels in Treatment Cycle 3
Measure Description	Blood samples for assessment of serum LH were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**190**
Serum LH Levels in Treatment Cycle 3 [units: IU/L] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=185)	**5.05 (1.97)**
Stimulation Day 5 or 6 (n=186)	**4.84 (5.39)**
Stimulation Day 8 (n=184)	**1.36 (1.50)**
Day of (rec)hCG injection (n=183)	**1.79 (2.71)**
Day of embryo transfer (n=168)	**NA [1]**
2 weeks after embryo transfer (n=173)	**3.57 (3.13)**

[1] If more than 1/3 of the values per assessment day were smaller than the LLOQ of the analytical method (0.6 IU/L), mean and SD are reported as missing.

No statistical analysis provided for Serum LH Levels in Treatment Cycle 3

61. Secondary: Serum Estradiol Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Serum Estradiol Levels in Treatment Cycle 1
Measure Description	Blood samples for assessment of serum estradiol were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**658**
Serum Estradiol Levels in Treatment Cycle 1 **[units: pmol/L]** **Mean (Standard Deviation)**	
Stimulation Day 1 (pre-dose) (n=651)	**126.07 (74.36)**
Stimulation Day 5 or 6 (n=648)	**2246.72 (1479.01)**
Stimulation Day 8 (n=633)	**3224.72 (2013.62)**
Day of (rec)hCG injection (n=642)	**5602.90 (3400.47)**
Day of embryo transfer (n=593)	**2972.22 (1758.83)**
2 weeks after embryo transfer (n=611)	**1064.92 (2006.31)**

No statistical analysis provided for Serum Estradiol Levels in Treatment Cycle 1

62. Secondary: Serum Estradiol Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Serum Estradiol Levels in Treatment Cycle 2
Measure Description	Blood samples for assessment of serum estradiol were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**364**
Serum Estradiol Levels in Treatment Cycle 2 **[units: pmol/L]** **Mean (Standard Deviation)**	
Stimulation Day 1 (pre-dose) (n=357)	**120.80 (43.73)**
Stimulation Day 5 or 6 (n=357)	**2116.13 (1362.31)**
Stimulation Day 8 (n=346)	**3197.12 (2098.53)**
Day of (rec)hCG injection (n=358)	**5444.89 (2992.37)**
Day of embryo transfer (n=324)	**2988.11 (1823.81)**
2 weeks after embryo transfer (n=333)	**929.24 (1861.04)**

No statistical analysis provided for Serum Estradiol Levels in Treatment Cycle 2

63. Secondary: Serum Estradiol Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Serum Estradiol Levels in Treatment Cycle 3
Measure Description	Blood samples for assessment of serum estradiol were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection

	of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	190
Serum Estradiol Levels in Treatment Cycle 3 [units: pmol/L] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=185)	117.5 (42.10)
Stimulation Day 5 or 6 (n=185)	1993.66 (1372.67)
Stimulation Day 8 (n=184)	3164.08 (2214.33)
Day of (rec)hCG injection (n=183)	5605.89 (3687.99)
Day of embryo transfer (n=168)	3065.47 (1988.36)
2 weeks after embryo transfer (n=172)	746.52 (1249.66)

No statistical analysis provided for Serum Estradiol Levels in Treatment Cycle 3

64. Secondary: Serum Progesterone Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Serum Progesterone Levels in Treatment Cycle 1
Measure Description	Blood samples for assessment of serum progesterone were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal

	phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	**658**
Serum Progesterone Levels in Treatment Cycle 1 [units: nmol/L] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=651)	**1.99 (2.40)**
Stimulation Day 5 or 6 (n=648)	**2.72 (11.85)**
Stimulation Day 8 (n=633)	**1.85 (2.00)**
Day of (rec)hCG injection (n=643)	**4.14 (23.37)**
Day of embryo transfer (n=593)	**331.16 (169.05)**
2 weeks after embryo transfer (n=611)	**100.31 (168.53)**

No statistical analysis provided for Serum Progesterone Levels in Treatment Cycle 1

65. Secondary: Serum Progesterone Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Serum Progesterone Levels in Treatment Cycle 2
Measure Description	Blood samples for assessment of serum progesterone were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	364
Serum Progesterone Levels in Treatment Cycle 2 [units: nmol/L] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=357)	1.84 (1.64)
Stimulation Day 5 or 6 (n=358)	2.14 (1.13)
Stimulation Day 8 (n=346)	1.75 (1.09)
Day of (rec)hCG injection (n=358)	3.91 (9.14)
Day of embryo transfer (n=325)	316.28 (174.25)
2 weeks after embryo transfer (n=333)	88.21 (165.39)

No statistical analysis provided for Serum Progesterone Levels in Treatment Cycle 2

66. Secondary: Serum Progesterone Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Serum Progesterone Levels in Treatment Cycle 3
Measure Description	Blood samples for assessment of serum progesterone were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed	190

[units: participants]	
Serum Progesterone Levels in Treatment Cycle 3 **[units: nmol/L]** **Mean (Standard Deviation)**	
Stimulation Day 1 (pre-dose) (n=185)	**1.76 (0.74)**
Stimulation Day 5 or 6 (n=186)	**2.29 (3.37)**
Stimulation Day 8 (n=184)	**1.75 (0.74)**
Day of (rec)hCG injection (n=183)	**4.92 (14.81)**
Day of embryo transfer (n=168)	**311.64 (161.71)**
2 weeks after embryo transfer (n=173)	**79.03 (136.60)**

No statistical analysis provided for Serum Progesterone Levels in Treatment Cycle 3

67. Secondary: Serum Inhibin-B Levels in Treatment Cycle 1 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1]

Measure Type	Secondary
Measure Title	Serum Inhibin-B Levels in Treatment Cycle 1
Measure Description	Blood samples for assessment of serum inhibin-B were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 1

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed **[units: participants]**	**658**
Serum Inhibin-B Levels in Treatment Cycle 1	

[units: pg/mL] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=652)	48.22 (29.91)
Stimulation Day 5 or 6 (n=648)	409.63 (299.19)
Stimulation Day 8 (n=634)	455.46 (372.09)
Day of (rec)hCG injection (n=643)	523.07 (464.36)
Day of embryo transfer (n=591)	NA [1]
2 weeks after embryo transfer (n=611)	NA [1]

[1] If more than 1/3 of the values per assessment day were smaller than the LLOQ of the analytical method (10 pg/mL), mean and SD are reported as missing.

No statistical analysis provided for Serum Inhibin-B Levels in Treatment Cycle 1

68. Secondary: Serum Inhibin-B Levels in Treatment Cycle 2 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2]

Measure Type	Secondary
Measure Title	Serum Inhibin-B Levels in Treatment Cycle 2
Measure Description	Blood samples for assessment of serum inhibin-B were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 2
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 2

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	364
Serum Inhibin-B Levels in Treatment Cycle 2 [units: pg/mL]	

Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=356)	48.88 (26.79)
Stimulation Day 5 or 6 (n=358)	406.29 (326.64)
Stimulation Day 8 (n=346)	443.32 (402.67)
Day of (rec)hCG injection (n=358)	505.02 (432.96)
Day of embryo transfer (n=325)	29.38 (34.99)
2 weeks after embryo transfer (n=333)	39.04 (33.74)

No statistical analysis provided for Serum Inhibin-B Levels in Treatment Cycle 2

69. Secondary: Serum Inhibin-B Levels in Treatment Cycle 3 [Time Frame: Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3]

Measure Type	Secondary
Measure Title	Serum Inhibin-B Levels in Treatment Cycle 3
Measure Description	Blood samples for assessment of serum inhibin-B were taken pre-dose (Stimulation Day 1), Stimulation Day 5 or 6 (prior to first GnRH antagonist administration), Stimulation Day 8, day of (rec)hCG administration, day of ET and 2 weeks after ET.
Time Frame	Pre-dose (Stimulation Day 1) through 2 weeks after ET in Treatment Cycle 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received corifollitropin alfa and (rec)hCG injection in Treatment Cycle 3

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Measured Values

	Corifollitropin Alfa 150 µg
Number of Participants Analyzed [units: participants]	190
Serum Inhibin-B Levels in Treatment Cycle 3 [units: pg/mL] Mean (Standard Deviation)	
Stimulation Day 1 (pre-dose) (n=185)	50.49 (28.25)
Stimulation Day 5 or 6 (n=186)	406.14 (331.91)

Stimulation Day 8 (n=184)	**439.83 (374.99)**
Day of (rec)hCG injection (n=183)	**504.03 (437.68)**
Day of embryo transfer (n=168)	**26.28 (25.03)**
2 weeks after embryo transfer (n=173)	**40.16 (34.05)**

No statistical analysis provided for Serum Inhibin-B Levels in Treatment Cycle 3

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to approximately 26 months after first dose of corifollitropin alfa
Additional Description	SAEs that occurred in fetuses or infants during the study period are included in the summary of SAEs, and are allocated to the associated study participant who was administered corifollitropin alfa.

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Serious Adverse Events

	Corifollitropin Alfa 150 µg
Total, serious adverse events	
# participants affected / at risk	**51/682 (7.48%)**
Congenital, familial and genetic disorders	
Autosomal chromosome anomaly † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**2**
Congenital arterial malformation † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Congenital uterine anomaly † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Cytogenetic abnormality † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Ectopia cordis † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**

Encephalocele † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Trisomy 15 † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Eye disorders	
Conjunctivitis † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Gastrointestinal disorders	
Abdominal pain † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Peritoneal haemorrhage † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Hepatobiliary disorders	
Cholelithiasis † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Infections and infestations	
Appendicitis † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Post procedural infection † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Pyelonephritis † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Respiratory tract infection viral † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Injury, poisoning and procedural complications	
Head injury † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Musculoskeletal and connective tissue disorders	
Growth retardation † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**
Intervertebral disc protrusion † 1	
# participants affected / at risk	**1/682 (0.15%)**

# events	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Teratoma † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Uterine leiomyoma † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Pregnancy, puerperium and perinatal conditions	
Abortion missed † 1	
# participants affected / at risk	3/682 (0.44%)
# events	3
Abortion spontaneous † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Abortion threatened † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Arrested labour † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Breech presentation † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Ectopic pregnancy † 1	
# participants affected / at risk	8/682 (1.17%)
# events	8
Foetal distress syndrome † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Heterotopic pregnancy † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Hyperemesis gravidarum † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Imminent abortion † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Placenta praevia haemorrhage † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Premature baby † 1	
# participants affected / at risk	3/682 (0.44%)

# events	5
Premature labour † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Premature rupture of membranes † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Retroplacental haematoma † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Ruptured ectopic pregnancy † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Small for dates baby † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Twin pregnancy † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Psychiatric disorders	
Psychosomatic disease † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Reproductive system and breast disorders	
Endometriosis † 1	
# participants affected / at risk	2/682 (0.29%)
# events	2
Fallopian tube disorder † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Ovarian haematoma † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Ovarian hyperstimulation syndrome † 1	
# participants affected / at risk	10/682 (1.47%)
# events	10
Pelvic pain † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Uterine cervix stenosis † 1	
# participants affected / at risk	1/682 (0.15%)
# events	1
Respiratory, thoracic and mediastinal disorders	
Pulmonary embolism † 1	
# participants affected / at risk	1/682 (0.15%)

# events	**1**
Surgical and medical procedures	
Gastric stapling reversal † 1	
# participants affected / at risk	**1/682 (0.15%)**
# events	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to approximately 26 months after first dose of corifollitropin alfa
Additional Description	SAEs that occurred in fetuses or infants during the study period are included in the summary of SAEs, and are allocated to the associated study participant who was administered corifollitropin alfa.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Corifollitropin Alfa 150 µg	Up to 3 COS cycles (also called treatment cycles) were performed, each including the following: A single injection of 150 µg corifollitropin alfa was administered on Day 2 or 3 of the menstrual cycle (Stimulation Day 1). Administration of GnRH antagonist (0.25 mg/day) started on Stimulation Day 5 or 6 and continued through day of administration of (rec)hCG (5,000-10,000 IU/250 µg). Daily dosing with FSH (not to exceed 225 IU/day) began on Stimulation Day 8 and continued up to day of (rec)hCG administration. Progesterone was administered for luteal phase support. After COS cycles 1 and 2, FTET cycles (up to 3 after each COS cycle) could occur.

Other Adverse Events

	Corifollitropin Alfa 150 µg
Total, other (not including serious) adverse events	
# participants affected / at risk	**239/682 (35.04%)**
Injury, poisoning and procedural complications	
Procedural pain † 1	
# participants affected / at risk	**121/682 (17.74%)**
# events	**163**
Nervous system disorders	
Headache † 1	
# participants affected / at risk	**62/682 (9.09%)**
# events	**91**
Pregnancy, puerperium and perinatal conditions	
Abortion spontaneous † 1	
# participants affected / at risk	**48/682 (7.04%)**

# events	**51**
Reproductive system and breast disorders	
Pelvic discomfort † 1	
# participants affected / at risk	**35/682 (5.13%)**
# events	**39**
Pelvic pain † 1	
# participants affected / at risk	**51/682 (7.48%)**
# events	**60**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☐ 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**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ 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 **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** Publications must be based on data validated and released by the Sponsor. Any scientific paper, presentation, or other communication concerning the study must first be submitted to the Sponsor, at least 6 weeks prior to estimated publication or presentation, for written consent. Sponsor has the right to make its consent conditional upon proper representation of the interpretation of both the Sponsor and the Investigator in the discussion of the data in such communications.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Rombauts L, Lambalk CB, Schultze-Mosgau A, van Kuijk J, Verweij P, Gates D, Gordon K, Griesinger G. Intercycle variability of the ovarian

response in patients undergoing repeated stimulation with corifollitropin alfa in a gonadotropin-releasing hormone antagonist protocol. Fertil Steril. 2015 Oct;104(4):884-890.e2. doi: 10.1016/j.fertnstert.2015.06.027. Epub 2015 Jul 15.

Norman RJ, Zegers-Hochschild F, Salle BS, Elbers J, Heijnen E, Marintcheva-Petrova M, Mannaerts B; Trust Investigators. Repeated ovarian stimulation with corifollitropin alfa in patients in a GnRH antagonist protocol: no concern for immunogenicity. Hum Reprod. 2011 Aug;26(8):2200-8. doi: 10.1093/humrep/der163. Epub 2011 May 27.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00696878 History of Changes
Other Study ID Numbers:	P05714 MK-8962-007 (Other Identifier: Merck Study Number) 38825 (Other Identifier: Merck Study Number) 2004-004966-34 (EudraCT Number)
Study First Received:	June 11, 2008
Results First Received:	April 6, 2015
Last Updated:	May 20, 2015
Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Australia: Department of Health and Ageing Therapeutic Goods Administration Brazil: National Health Surveillance Agency Chile: Instituto de Salud Pública de Chile Denmark: Danish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: German Institute of Medical Documentation and Information Hungary: National Institute of Pharmacy Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Norway: Norwegian Medicines Agency Sweden: Medical Products Agency United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK