Follow-up Study of Frozen-thawed Embryo Transfer (FTET) Cycles After Cryopreservation of Embryos in Clinical Trial P05787 (P05716)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00702273

First received: June 18, 2008
Last updated: November 18, 2014
Last verified: November 2014
History of Changes

Purpose

To collect the outcome of frozen-thawed embryo transfer cycles after the embryos are cryopreserved up to at least 1 year in Trial P05787 (NCT00696800), in order to estimate the cumulative pregnancy rate for each treatment group.

Condition	Intervention
In Vitro Fertilization	Drug: 150 µg Corifollitropin Alfa Biological: 200 IU RecFSH/Follitropin beta (Days 1 to 7) Drug: Placebo for Corifollitropin Alfa Drug: Placebo for RecFSH/Follitropin beta Biological: 200 IU RecFSH/Follitropin beta (Days 8 to hCG) Drug: Ganirelix Biological: hCG Biological: Progesterone

Study Type: Observational
Study Design: Time Perspective: Prospective

Official Title: Follow-up Protocol to Collect the Outcome of Frozen-thawed Embryo Transfer Cycles After Cryopreservation of Embryos in Clinical Trial 38819

Resource links provided by NLM:

Drug Information available for: Progesterone Ganirelix Ganirelix acetate

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants With an Ongoing Pregnancy (Cumulative Ongoing Pregnancy Rate) [Time Frame: Up to 1 year after embryo transfer in base trial P05787 (NCT00696800), and FTET cycles in follow up trial] [Designated as safety issue: No]

  An ongoing pregnancy is the presence of at least one fetus with heart activity at least 10 weeks after embryo transfer or confirmed by live birth.The cumulative ongoing pregnancy rate is 100 times the number of participants with an ongoing pregnancy either immediately after embryo transfer in base Trial P05787 (NCT00696800), or after one or more FTET cycles in follow-up Trial P05716 following cryopreservation, divided by the total number of participants that started treatment in base Trial P05787 (NCT00696800). Participants who did not have cryopreserved embryos, or embryo transfers in the FTET cycle(s), were considered 'not pregnant'.

Secondary Outcome Measures:

- Percentage of Participants in Follow up Trial With a Miscarriage Per Clinical Pregnancy [Time Frame: After one or more FTET cycles, up to day of miscarriage (up to 1 year)] [Designated as safety issue: No]

  Miscarriages were calculated per clinical pregnancy, meaning the presence of at least one gestational sac or confirmed by live birth.

- Percentage of Participants in Follow up Trial With a Miscarriage Per Vital Pregnancy [Time Frame: After one or more FTET cycles, up to day of miscarriage (up to 1 year)] [Designated as safety issue: No]

  Miscarriages were calculated per vital pregnancy, meaning the presence of at least one fetus with heart activity.

- Percentage of Participants in Follow up Trial With an Ectopic Pregnancy [Time Frame: After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)] [Designated as safety issue: No]

  An ectopic pregnancy is where the embryo implants outside the uterus. Ectopic pregnancies were calculated per total number of participants started in FTET.

- Percentage of Participants in Follow up Trial With a Clinical Pregnancy [Time Frame: After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)] [Designated as safety issue: No]

  A clinical pregnancy is the presence of at least gestational sac or confirmed by live birth. Clinical pregnancies were calculated per attempt, meaning if any stage of in vitro fertilization (IVF) treatment was not achieved, zero values were imputed.

- Percentage of Participants in Follow up Trial With a Vital Pregnancy [Time Frame: After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)] [Designated as safety issue: No]

  A vital pregnancy is the presence of at least one fetus with heart activity. Vital pregnancies were calculated per attempt, meaning if any stage of IVF treatment was not achieved, zero values were imputed.

- Percentage of Participants in Follow up Trial With an Ongoing Pregnancy [Time Frame: After one or more FTET, assessed at least 10 weeks after embryo transfer or at live birth (up to 1 year)] [Designated as safety issue: No]

  An ongoing pregnancy is the presence of at least one fetus with heart activity at least 10 weeks after embryo transfer or confirmed at live birth. Ongoing pregnancies were calculated per attempt, meaning if any stage of IVF treatment was not achieved, zero values were imputed.

Enrollment:	344
Study Start Date:	September 2006
Study Completion Date:	May 2009
Primary Completion Date:	May 2009 (Final data collection date for primary outcome measure)

Groups/Cohorts	Assigned Interventions
150 µg Corifollitropin Alfa Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa (Org 36286) on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recombinant Follicle Stimulating Hormone (recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.	Drug: 150 µg Corifollitropin Alfa On the morning of day 2 or 3 of the menstrual cycle (Stimulation Day 1), a single SC injection of 150 µg (0.5 mL) Corifollitropin Alfa was administered in the abdominal wall. Drug: Placebo for RecFSH/Follitropin beta

	Identical ready-for-use solution, but without the active ingredient, supplied in cartridges for SC injection with the Follistim Pen. Daily SC injections were started on Stimulation Day 1 and continued up to and including Stimulation Day 7. Biological: 200 IU RecFSH/Follitropin beta (Days 8 to hCG) From Stimulation Day 8 onwards a daily SC dose of 200 IU recFSH was administered up to and including the Day of hCG. Drug: Ganirelix On Stimulation Day 5 a daily SC injection of 0.25 mg was started, which continued up to and including the day of hCG Biological: hCG When 3 follicles >= 17 mm were observed by USS, a single dose of 10,000 IU/USP hCG was administered; or, for those at risk for Ovarian Hyperstimulation Syndrome (OHSS), a lower dose of 5,000 IU/USP Biological: Progesterone On the day of OPU, luteal phase support was started by administering micronized progesterone of at least 600 mg/day vaginally, or at least 50 mg/day intramuscular (IM), which continued for at least 6 weeks, or up to menses.
200 IU RecFSH Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.	Biological: 200 IU RecFSH/Follitropin beta (Days 1 to 7) Daily SC injections with 200 IU fixed dose recFSH were started on Stimulation Day 1 and continued up to and including Stimulation Day 7. Drug: Placebo for Corifollitropin Alfa Pre-filled syringe containing an identical solution when compared to Corifollitropin Alfa. On the morning of day 2 or 3 of the menstrual cycle (Stimulation Day 1), a single SC injection was

	administered in the abdominal wall. Biological: 200 IU RecFSH/Follitropin beta (Days 8 to hCG) From Stimulation Day 8 onwards a daily SC dose of 200 IU recFSH was administered up to and including the Day of hCG. Drug: Ganirelix On Stimulation Day 5 a daily SC injection of 0.25 mg was started, which continued up to and including the day of hCG Biological: hCG When 3 follicles >= 17 mm were observed by USS, a single dose of 10,000 IU/USP hCG was administered; or, for those at risk for Ovarian Hyperstimulation Syndrome (OHSS), a lower dose of 5,000 IU/USP Biological: Progesterone On the day of OPU, luteal phase support was started by administering micronized progesterone of at least 600 mg/day vaginally, or at least 50 mg/day intramuscular (IM), which continued for at least 6 weeks, or up to menses.

Detailed Description:

This is a follow-up protocol to collect the outcome of frozen-thawed embryo transfer cycles, performed after the embryos are cryopreserved up to at least 1 year in Trial P05787 (NCT00696800), to enable estimation of the cumulative pregnancy rate for each treatment group.

Eligibility

Ages Eligible for Study:	18 Years to 36 Years
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population

Women from whom embryos have been cryopreserved in Base Trial P05787 (NCT00696800).

Criteria

Inclusion Criteria:

- Participants from whom embryos have been cryopreserved in Base Trial P05787 (NCT00696800), of which at least one embryo is thawed for use in a subsequent FTET cycle;
- Able and willing to give informed consent.

Exclusion Criteria:

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.

No Contacts or Locations Provided

More Information

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

Boostanfar R, Mannaerts B, Pang S, Fernandez-Sanchez M, Witjes H, Devroey P; Engage Investigators. A comparison of live birth rates and cumulative ongoing pregnancy rates between Europe and North America after ovarian stimulation with corifollitropin alfa or recombinant follicle-stimulating hormone. Fertil Steril. 2012 Jun;97(6):1351-8. doi: 10.1016/j.fertnstert.2012.02.038. Epub 2012 Mar 28.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00702273 History of Changes
Other Study ID Numbers:	P05716 2004-004773-28 38831 MK-8962-009
Study First Received:	June 18, 2008
Results First Received:	May 14, 2014
Last Updated:	November 18, 2014
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
In-vitro fertilization
Controlled Ovarian Stimulation
Cumulative pregnancy data
Follow-up

Additional relevant MeSH terms:
Follicle Stimulating Hormone
Ganirelix
Progesterone
Hormone Antagonists
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Pharmacologic Actions
Physiological Effects of Drugs
Progestins

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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

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First received: June 18, 2008
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History of Changes

Results First Received: May 14, 2014

Study Type:	Observational
Study Design:	Time Perspective: Prospective
Condition:	In Vitro Fertilization
Interventions:	Drug: 150 µg Corifollitropin Alfa Biological: 200 IU RecFSH/Follitropin beta (Days 1 to 7) Drug: Placebo for Corifollitropin Alfa Drug: Placebo for RecFSH/Follitropin beta Biological: 200 IU RecFSH/Follitropin beta (Days 8 to hCG) Drug: Ganirelix Biological: hCG Biological: 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

Period one consists of participants from the base study P05787 (NCT00696800), randomized to treatment groups Corifollitropin Alfa (Cori Alfa) (Org 36286) or recombinant Follicle Stimulating Hormone (recFSH). Period two consists of eligible participants (N = 344) from the base study who enrolled in the follow up study P05716.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent frozen thawed embryo transfer (FTET) cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Participant Flow for 2 periods

Period 1: Base Study P05787 (NCT00696800)

	150 µg Corifollitropin Alfa	200 IU RecFSH
STARTED	**757** [1]	**752** [1]
Treated	**756** [2]	**750** [2]
COMPLETED	**672** [3]	**704** [3]
NOT COMPLETED	**85**	**48**

[1] Participants randomized to the base study P05787 (NCT00696800)
[2] Participants from the Intent to Treat group (ITT) from the base study P05787 (NCT00696800)
[3] To complete study, participants from the base study P05787 (NCT00696800) had embryos transferred

Period 2: Follow Up Study P05716 (NCT00702273)

	150 µg Corifollitropin Alfa	200 IU RecFSH
STARTED	**168** [1]	**176** [2]
COMPLETED	**148** [3]	**147** [3]
NOT COMPLETED	**20**	**29**

[1] Participants from base study,who had at least one embryo thawed for a FTET cycle.
[2] Participants from base study, who had at least one embryo thawed for a FTET cycle
[3] Participants with embryo transfer in any FTET cycle

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.
Eligible participants from base study P05787 (NCT00696800) who enrolled in follow up study P05716

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
Total	Total of all reporting groups

Baseline Measures

	150 µg Corifollitropin Alfa	**200 IU RecFSH**	**Total**
Number of Participants [units: participants]	**168**	**176**	**344**
Age [units: Years] Mean (Standard Deviation)	**31.1 (3.8)**	**31.3 (3.0)**	**31.2 (3.4)**
Gender [units: Participants]			
Female	**168**	**176**	**344**
Male	**0**	**0**	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With an Ongoing Pregnancy (Cumulative Ongoing Pregnancy Rate) [Time Frame: Up to 1 year after embryo transfer in base trial P05787 (NCT00696800), and FTET cycles in follow up trial]

Measure Type	Primary
Measure Title	Percentage of Participants With an Ongoing Pregnancy (Cumulative Ongoing Pregnancy Rate)
Measure Description	An ongoing pregnancy is the presence of at least one fetus with heart activity at least 10 weeks after embryo transfer or confirmed by live birth.The cumulative ongoing pregnancy rate is 100 times the number of participants with an ongoing pregnancy either immediately after embryo transfer in base Trial P05787 (NCT00696800), or after one or more FTET cycles in follow-up Trial P05716 following cryopreservation, divided by the total number of participants that started treatment in base Trial P05787 (NCT00696800). Participants who did not have cryopreserved embryos, or embryo

	transfers in the FTET cycle(s), were considered 'not pregnant'.
Time Frame	Up to 1 year after embryo transfer in base trial P05787 (NCT00696800), and FTET cycles in follow up trial
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.
ITT group from base trial P05787, consisting of randomized participants who were treated with Corifollitropin Alfa or recFSH.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Measured Values

	150 µg Corifollitropin Alfa	**200 IU RecFSH**
Number of Participants Analyzed [units: participants]	**756**	**750**
Percentage of Participants With an Ongoing Pregnancy (Cumulative Ongoing Pregnancy Rate) [units: Percentage of participants]	**47.2**	**44.9**

Statistical Analysis 1 for Percentage of Participants With an Ongoing Pregnancy (Cumulative Ongoing Pregnancy Rate)

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Risk Difference (RD) [3]	2.4
95% Confidence Interval	-2.6 to 7.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Treatment groups were compared with a generalized linear model including covariates treatment group, age class and region.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Non-inferiority margin of -8%
[3]	Other relevant estimation information:

	No text entered.

2. Secondary: Percentage of Participants in Follow up Trial With a Miscarriage Per Clinical Pregnancy [Time Frame: After one or more FTET cycles, up to day of miscarriage (up to 1 year)]

Measure Type	Secondary
Measure Title	Percentage of Participants in Follow up Trial With a Miscarriage Per Clinical Pregnancy
Measure Description	Miscarriages were calculated per clinical pregnancy, meaning the presence of at least one gestational sac or confirmed by live birth.
Time Frame	After one or more FTET cycles, up to day of miscarriage (up to 1 year)
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 enrolled in P05716 Follow Up study that had a clinical pregnancy.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Measured Values

	150 µg Corifollitropin Alfa	**200 IU RecFSH**
Number of Participants Analyzed [units: participants]	**73**	**68**
Percentage of Participants in Follow up Trial With a Miscarriage Per Clinical Pregnancy [units: Percentage of participants]	**8.2**	**17.6**

No statistical analysis provided for Percentage of Participants in Follow up Trial With a Miscarriage Per Clinical Pregnancy

3. Secondary: Percentage of Participants in Follow up Trial With a Miscarriage Per Vital Pregnancy [Time Frame: After one or more FTET cycles, up to day of miscarriage (up to 1 year)]

Measure Type	Secondary
Measure Title	Percentage of Participants in Follow up Trial With a Miscarriage Per Vital Pregnancy
Measure Description	Miscarriages were calculated per vital pregnancy, meaning the presence of at least one fetus with heart activity.
Time Frame	After one or more FTET cycles, up to day of miscarriage (up to 1 year)
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 enrolled in P05716 Follow Up study that had a vital pregnancy.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Measured Values

	150 µg Corifollitropin Alfa	**200 IU RecFSH**
Number of Participants Analyzed [units: participants]	**67**	**56**
Percentage of Participants in Follow up Trial With a Miscarriage Per Vital Pregnancy [units: Percentage of participants]	**0**	**0**

No statistical analysis provided for Percentage of Participants in Follow up Trial With a Miscarriage Per Vital Pregnancy

4. Secondary: Percentage of Participants in Follow up Trial With an Ectopic Pregnancy [Time Frame: After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)]

Measure Type	Secondary
Measure Title	Percentage of Participants in Follow up Trial With an Ectopic Pregnancy
Measure Description	An ectopic pregnancy is where the embryo implants outside the uterus. Ectopic pregnancies were calculated per total number of participants started in FTET.

Time Frame	After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)
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 enrolled in P05716 Follow Up study.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
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Measured Values

	150 µg Corifollitropin Alfa	**200 IU RecFSH**
Number of Participants Analyzed [units: participants]	**168**	**176**
Percentage of Participants in Follow up Trial With an Ectopic Pregnancy [units: Percentage of participants]	**1.2**	**0.6**

No statistical analysis provided for Percentage of Participants in Follow up Trial With an Ectopic Pregnancy

5. Secondary: Percentage of Participants in Follow up Trial With a Clinical Pregnancy [Time Frame: After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)]

Measure Type	Secondary
Measure Title	Percentage of Participants in Follow up Trial With a Clinical Pregnancy
Measure Description	A clinical pregnancy is the presence of at least gestational sac or confirmed by live birth. Clinical pregnancies were calculated per attempt, meaning if any stage of in vitro fertilization (IVF) treatment was not achieved, zero values were imputed.
Time Frame	After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)
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 enrolled in P05716 Follow Up study, that had an embryo transfer in the respective cycle.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Measured Values

	150 µg Corifollitropin Alfa	200 IU RecFSH
Number of Participants Analyzed [units: participants]	**168**	**176**
Percentage of Participants in Follow up Trial With a Clinical Pregnancy [units: Percentage of participants]	**43.5**	**38.6**

No statistical analysis provided for Percentage of Participants in Follow up Trial With a Clinical Pregnancy

6. Secondary: Percentage of Participants in Follow up Trial With a Vital Pregnancy [Time Frame: After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)]

Measure Type	Secondary
Measure Title	Percentage of Participants in Follow up Trial With a Vital Pregnancy
Measure Description	A vital pregnancy is the presence of at least one fetus with heart activity. Vital pregnancies were calculated per attempt, meaning if any stage of IVF treatment was not achieved, zero values were imputed.
Time Frame	After one or more FTET cycles, assessed at least 10 weeks after embryo transfer (up to 1 year)
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 enrolled in P05716 Follow Up study, that had an embryo transfer in the respective cycle.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Measured Values

	150 µg Corifollitropin Alfa	200 IU RecFSH
Number of Participants Analyzed [units: participants]	**168**	**176**
Percentage of Participants in Follow up Trial With a Vital Pregnancy [units: Percentage of participants]	**39.9**	**31.8**

No statistical analysis provided for Percentage of Participants in Follow up Trial With a Vital Pregnancy

7. Secondary: Percentage of Participants in Follow up Trial With an Ongoing Pregnancy [Time Frame: After one or more FTET, assessed at least 10 weeks after embryo transfer or at live birth (up to 1 year)]

Measure Type	Secondary
Measure Title	Percentage of Participants in Follow up Trial With an Ongoing Pregnancy
Measure Description	An ongoing pregnancy is the presence of at least one fetus with heart activity at least 10 weeks after embryo transfer or confirmed at live birth. Ongoing pregnancies were calculated per attempt, meaning if any stage of IVF treatment was not achieved, zero values were imputed.
Time Frame	After one or more FTET, assessed at least 10 weeks after embryo transfer or at live birth (up to 1 year)
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 enrolled in P05716 Follow Up study, that had an embryo transfer in the respective cycle.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was

	given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Measured Values

	150 µg Corifollitropin Alfa	200 IU RecFSH
Number of Participants Analyzed [units: participants]	**168**	**176**
Percentage of Participants in Follow up Trial With an Ongoing Pregnancy [units: Percentage of participants]	**38.7**	**30.7**

No statistical analysis provided for Percentage of Participants in Follow up Trial With an Ongoing Pregnancy

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Participants who enrolled in Trial P05716 Follow Up. Trial P05716 did not systematically collect Serious Adverse Events (SAEs) or AEs. Instead any reported AEs were unsolicited and non-systematically assessed. Ectopic pregnancies in Outcome Measure 4 were collected as an efficacy rather than a safety endpoint; and were therefore not counted as AEs.

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Serious Adverse Events

	150 µg Corifollitropin Alfa	200 IU RecFSH

Total, serious adverse events		
# participants affected / at risk	**1/168 (0.60%)**	**0/176 (0.00%)**
Pregnancy, puerperium and perinatal conditions		
Ectopic pregnancy * 1		
# participants affected / at risk	**1/168 (0.60%)**	**0/176 (0.00%)**
# events	**1**	**0**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Participants who enrolled in Trial P05716 Follow Up. Trial P05716 did not systematically collect Serious Adverse Events (SAEs) or AEs. Instead any reported AEs were unsolicited and non-systematically assessed. Ectopic pregnancies in Outcome Measure 4 were collected as an efficacy rather than a safety endpoint; and were therefore not counted as AEs.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
150 µg Corifollitropin Alfa	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on menstrual cycle Day 2/3 (Day 1); 7 daily SC injections from Days 1 to 7 with placebo-recFSH); followed by daily SC injections with 200 IU recFSH up to the day of human chorionogonadotropin (hCG). Daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of oocyte pick up (OPU) daily doses of progesterone were started, for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.
200 IU RecFSH	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day 2/3 (Day 1); 7 daily SC injections with 200 IU recFSH from Days 1 to 7; followed by daily SC injections with 200 IU recFSH up to the day of hCG. Multiple daily SC injections of Ganirelix were given from Day 5 to the day of hCG; at which time a single dose of hCG was given when 3 follicles >= 17 mm. On the day of OPU daily doses of progesterone were started and continued for up to 6 weeks or menses. Eligible participants from the base study were enrolled in follow up study P05716, where no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

Other Adverse Events

	150 µg Corifollitropin Alfa	**200 IU RecFSH**
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/168 (0.00%)**	**0/176 (0.00%)**

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:** Any scientific paper, presentation, or other communication concerning the clinical trial will first be submitted to the Sponsor, at least six weeks ahead of estimated publication or presentation, for written consent, which shall not be withheld unreasonably. The Sponsor shall have the right to make its consent conditional upon proper representation of the interpretation of both the Sponsor and the investigator(s) in the discussion of the data in such communications.

Results Point of Contact:

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Boostanfar R, Mannaerts B, Pang S, Fernandez-Sanchez M, Witjes H, Devroey P; Engage Investigators. A comparison of live birth rates and cumulative ongoing pregnancy rates between Europe and North America after ovarian stimulation with corifollitropin alfa or recombinant follicle-stimulating hormone. Fertil Steril. 2012 Jun;97(6):1351-8. doi: 10.1016/j.fertnstert.2012.02.038. Epub 2012 Mar 28.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00702273 History of Changes
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Last Updated:	November 18, 2014
Health Authority:	United States: Food and Drug Administration

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

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