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

ClinicalTrials.gov Identifier: NCT00702273

Recruitment Status : Completed
First Posted : June 20, 2008
Results First Posted : November 20, 2014
Last Update Posted : April 18, 2017

Sponsor:
Merck Sharp & Dohme Corp.

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

Study Description

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Brief Summary:
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 or disease	Intervention/treatment
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

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.

Study Design

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Study Type :	Observational
Actual Enrollment :	344 participants
Observational Model:	Other
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
Actual Study Start Date :	April 19, 2006
Actual Primary Completion Date :	May 19, 2009
Actual Study Completion Date :	May 31, 2009

Groups and Cohorts

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Group/Cohort	Intervention/treatment
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.

Outcome Measures

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Primary Outcome Measures :

1. 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]

   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 :

1. 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)]

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

2. 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)]

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

3. 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)]

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

4. 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)]

   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.

5. 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)]

   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.

6. 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)]

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.

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

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, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 36 Years (Adult)
Sexes 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

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No Contacts or Locations Provided

More Information

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Study Data/Documents: CSR Synopsis EXIT

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 (EudraCT Number)

	38831 (Other Identifier: Organon)
	MK-8962-009 (Other Identifier: Merck)
First Posted:	June 20, 2008 Key Record Dates
Results First Posted:	November 20, 2014
Last Update Posted:	April 18, 2017
Last Verified:	March 2017

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

Additional relevant MeSH terms:

Progesterone	Hormones
Follicle Stimulating Hormone	Hormones, Hormone Substitutes, and Hormone Antagonists
Ganirelix	Physiological Effects of Drugs
Progestins	Hormone Antagonists

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

Study Type	Observational
Study Design	Observational Model: Other; 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
Enrollment	344

Participant Flow

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Recruitment Details	
Pre-assignment Details	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.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description	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.	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.
Period Title: **Base Study P05787 (NCT00696800)**		
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 Title: **Follow Up Study P05716 (NCT00702273)**		
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

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Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH	Total
▼ Arm/Group Description	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	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	Total of all reporting groups

		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.	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.	
Overall Number of Baseline Participants		168	176	344
▼ Baseline Analysis Population Description		Eligible participants from base study P05787 (NCT00696800) who enrolled in follow up study P05716		
Age, Continuous Mean (Standard Deviation) Unit of measure: Years				
	Number Analyzed	168 participants	176 participants	344 participants
		31.1 (3.8)	31.3 (3.0)	31.2 (3.4)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	168 participants	176 participants	344 participants
	Female	168 100.0%	176 100.0%	344 100.0%
	Male	0 0.0%	0 0.0%	0 0.0%

Outcome Measures

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1. Primary Outcome

Title	Percentage of Participants With an Ongoing Pregnancy (Cumulative Ongoing Pregnancy Rate)
▼ 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

▼ Outcome Measure Data

▼ Analysis Population Description

ITT group from base trial P05787, consisting of randomized participants who were treated with Corifollitropin Alfa or recFSH.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description:	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.	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.
Overall Number of Participants Analyzed	756	750
Measure Type: Number Unit of Measure: Percentage of participants		
	47.2	44.9

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	150 µg Corifollitropin Alfa, 200 IU RecFSH
	Comments	Treatment groups were compared with a generalized linear model including covariates treatment group, age class and region.
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	Non-inferiority margin of -8%
Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	2.4
	Confidence Interval	(2-Sided) 95% -2.6 to 7.4
	Estimation Comments	[Not Specified]

2. Secondary Outcome

Title	Percentage of Participants in Follow up Trial With a Miscarriage Per Clinical Pregnancy
▼ 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)

▼ Outcome Measure Data

▼ Analysis Population Description
Participants enrolled in P05716 Follow Up study that had a clinical pregnancy.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description:	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.	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.
Overall Number of Participants Analyzed	73	68
Measure Type: Number Unit of Measure: Percentage of participants		
	8.2	17.6

3. Secondary Outcome

Title	Percentage of Participants in Follow up Trial With a Miscarriage Per Vital Pregnancy
▼ 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)

▼ Outcome Measure Data

▼ Analysis Population Description
Participants enrolled in P05716 Follow Up study that had a vital pregnancy.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description:	Participants from the base study P05787 (NCT00696800), received a single subcutaneous (SC) injection of 150 µg Corifollitropin Alfa on	Participants from the base study P05787 (NCT00696800), received a single SC injection of placebo Corifollitropin Alfa on menstrual cycle day

	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.	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.
Overall Number of Participants Analyzed	67	56
Measure Type: Number Unit of Measure: Percentage of participants		
	0	0

4. Secondary Outcome

Title	Percentage of Participants in Follow up Trial With an Ectopic Pregnancy
▼ 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)

▼ Outcome Measure Data

▼ Analysis Population Description
Participants enrolled in P05716 Follow Up study.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description:	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.	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.

Overall Number of Participants Analyzed	168	176
Measure Type: Number Unit of Measure: Percentage of participants		
	1.2	0.6

5. Secondary Outcome

Title	Percentage of Participants in Follow up Trial With a Clinical Pregnancy
▼ 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)

▼ Outcome Measure Data

▼ Analysis Population Description
Participants enrolled in P05716 Follow Up study, that had an embryo transfer in the respective cycle.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description:	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.	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.
Overall Number of Participants Analyzed	168	176
Measure Type: Number Unit of Measure: Percentage of participants		
	43.5	38.6

6. Secondary Outcome

Title	Percentage of Participants in Follow up Trial With a Vital Pregnancy

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)

Outcome Measure Data

Analysis Population Description
Participants enrolled in P05716 Follow Up study, that had an embryo transfer in the respective cycle.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
Arm/Group Description:	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.	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.
Overall Number of Participants Analyzed	168	176
Measure Type: Number Unit of Measure: Percentage of participants		
	39.9	31.8

7. Secondary Outcome

Title	Percentage of Participants in Follow up Trial With an Ongoing Pregnancy
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)

Outcome Measure Data

Analysis Population Description
Participants enrolled in P05716 Follow Up study, that had an embryo transfer in the respective cycle.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
Arm/Group Description:	Participants from the base study P05787 (NCT00696800), received a single subcutaneous	Participants from the base study P05787 (NCT00696800), received a single SC injection of

	(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.	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.
Overall Number of Participants Analyzed	168	176
Measure Type: Number Unit of Measure: Percentage of participants		
	38.7	30.7

Adverse Events

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Time Frame	[Not Specified]
Adverse Event Reporting 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.

Arm/Group Title	150 µg Corifollitropin Alfa	200 IU RecFSH
▼ Arm/Group Description	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	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

	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.	no study treatments were given, and embryos obtained in the base study underwent FTET cycles.

All-Cause Mortality

	150 µg Corifollitropin Alfa		200 IU RecFSH	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--	

Serious Adverse Events

	150 µg Corifollitropin Alfa		200 IU RecFSH	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	1/168 (0.60%)		0/176 (0.00%)	
Pregnancy, puerperium and perinatal conditions				
Ectopic pregnancy *1	1/168 (0.60%)	1	0/176 (0.00%)	0

* Indicates events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 12.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	150 µg Corifollitropin Alfa		200 IU RecFSH	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	0/168 (0.00%)		0/176 (0.00%)	

Limitations and Caveats

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[Not Specified]

More Information

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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.

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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