Pregnancy and Neonatal Follow-up of Ongoing Pregnancies Established in Clinical Trial P05690 (Care Program) (P05710) (Care)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00702624

First received: June 18, 2008
Last updated: December 11, 2015
Last verified: December 2015
History of Changes

Purpose

The objective of this follow-up study is to evaluate whether corifollitropin alfa (Org 36286) treatment for the induction of multifollicular growth in women undergoing controlled ovarian stimulation (COS) prior to in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) is safe for pregnant participants and their offspring.

Condition	Intervention
Pregnancy Neonates	Drug: Corifollitropin alfa Biological: recFSH (follitropin beta) Drug: gonadatropin releasing hormone (GnRH) antagonist ganirelix Biological: human chorion gonadotropin (hCG) Biological: progesterone Drug: placebo-recFSH (follitropin beta) Drug: placebo-corifollitropin alfa Biological: open-label recFSH (follitropin beta)

Study Type: Observational
Study Design: Time Perspective: Prospective

Official Title: Pregnancy and Neonatal Follow-up of Ongoing Pregnancies Established After Controlled Ovarian Stimulation in Clinical Trial 107012 for the Development of Org 36286 (Corifollitropin Alfa)

Resource links provided by NLM:

MedlinePlus related topics: Hormones

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 Women With ≥1 Live Born Infant During Follow-up (Take-Home Baby Rate) [Time Frame: From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)] [Designated as safety issue: No]

  The Take-Home Baby Rate was defined as the number of participants with an ongoing pregnancy in base study P05690 with at least one live born infant during follow up relative to the number of participants treated in base study.

- Number of Expectant Mothers Experiencing Adverse Events (AEs) [Time Frame: From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)] [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 Expectant Mothers Experiencing Serious AEs (SAEs) [Time Frame: From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)] [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.

- Number of Infants Experiencing AEs [Time Frame: Up to 12 weeks after birth] [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 can 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 Infants Experiencing SAEs [Time Frame: Up to 12 weeks after birth] [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.

Enrollment:	113
Study Start Date:	April 2007
Study Completion Date:	June 2008
Primary Completion Date:	April 2008 (Final data collection date for primary outcome measure)

Groups/Cohorts	Assigned Interventions
Corifollitropin alfa 100 µg In follow-up study, no medication or investigational product was administered. In base study P05690 (NCT00702845), participants received single subcutaneous (SC) injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo-recombinant Follicle Stimulating Hormone (recFSH) injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants in base study P05690 also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of Human Chorion Gonadotropin (hCG) administration. Participants also received Gonadotropin Releasing Hormone (GnRH) antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day by intramuscular [IM] injection), starting on day of oocyte pick-up (OPU) and continuing for at least 6 weeks or up to menses.	Drug: Corifollitropin alfa Single injection of 100 µg corifollitropin alfa administered under protocol P05690 Other Names: • SCH 900962 • MK-8962 Drug: gonadatropin releasing hormone (GnRH) antagonist ganirelix GnRH antagonist ganirelix administered SC at a

	dose of 0.25 mg/day under protocol P05690 Biological: human chorion gonadotropin (hCG) hCG 5,000 IU/USP or 10,000 IU/USP administered under protocol P05690 Biological: progesterone Under protocol P05690, progesterone was started on the day of oocyte pick-up (OPU) and continued for at least 6 weeks or up to menses. Participants received at least 600 mg/day vaginally or 50 mg/day IM. Drug: placebo-recFSH (follitropin beta) Placebo-recFSH at the equivalent volume of 150 IU/day administered under protocol P05690 Biological: open-label recFSH (follitropin beta) Open-label recFSH up to a maximum dose of 200 IU/day, administered under protocol P05690
recFSH 150 IU In follow-up study, no medication or investigational product was administered. In base study P05690 (NCT00702845), participants in the reference group received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG (10,000 or 5,000 IU/USP) administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG. Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the day of OPU and continuing for at least 6 weeks or up to menses.	Biological: recFSH (follitropin beta) Daily recFSH administered under protocol P05690 Other Names: • follitropin beta • Puregon® • Follistim® Drug: gonadatropin releasing hormone (GnRH) antagonist ganirelix GnRH antagonist ganirelix administered SC at a dose of 0.25 mg/day under protocol P05690

	Biological: human chorion gonadotropin (hCG) hCG 5,000 IU/USP or 10,000 IU/USP administered under protocol P05690 Biological: progesterone Under protocol P05690, progesterone was started on the day of oocyte pick-up (OPU) and continued for at least 6 weeks or up to menses. Participants received at least 600 mg/day vaginally or 50 mg/day IM. Drug: placebo-corifollitropin alfa Single SC injection of placebo-corifollitropin alfa on Day 2 or 3 of the menstrual cycle, administered under protocol P05690 Biological: open-label recFSH (follitropin beta) Open-label recFSH up to a maximum dose of 200 IU/day, administered under protocol P05690

Detailed Description:

This is a follow-up protocol to prospectively monitor pregnancy, delivery, and neonatal outcome of women who were treated with corifollitropin alfa or recFSH and became pregnant during the base study P05690 (NCT00702845). For this trial no study specific assessments are required, but information as obtained in standard practice will be used.

Eligibility

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

Study Population

Women with an ongoing pregnancy at least 10 weeks after embryo transfer in base study P05690 (NCT00702845) were enrolled in this trial.

Criteria

Inclusion Criteria:

- Participants who participated in base study P05690 (NCT00702845) and received at least one dose of either corifollitropin alfa (Org 36286) or recFSH in base study P05690;
- Ongoing pregnancy confirmed by ultrasound at least 10 weeks after embryo transfer in base study P05690;
- Able and willing to give written 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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00702624

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):

Bonduelle M, Mannaerts B, Leader A, Bergh C, Passier D, Devroey P. Prospective follow-up of 838 fetuses conceived after ovarian stimulation with corifollitropin alfa: comparative and overall neonatal outcome. Hum Reprod. 2012 Jul;27(7):2177-85. doi: 10.1093/humrep/des156. Epub 2012 May 15.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00702624 History of Changes
Other Study ID Numbers:	P05710 2006-003812-23 107014 MK-8962-003
Study First Received:	June 18, 2008
Results First Received:	April 13, 2015
Last Updated:	December 11, 2015
Health Authority:	Austria: Federal Office for Safety in Health Care Czech Republic: State Institute for Drug Control Denmark: Danish Medicines Agency Spain: Ministry of Health and Consumption France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Sweden: Medical Products Agency

Keywords provided by Merck Sharp & Dohme Corp.:
Neonatal outcome
Congenital malformations
In-Vitro fertilization
Controlled ovarian stimulation
Follow-up

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on May 08, 2016

TO TOP

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Results First Received: April 13, 2015

Study Type:	Observational
Study Design:	Time Perspective: Prospective
Conditions:	Pregnancy Neonates
Interventions:	Drug: Corifollitropin alfa Biological: recFSH (follitropin beta) Drug: gonadatropin releasing hormone (GnRH) antagonist ganirelix Biological: human chorion gonadotropin (hCG) Biological: progesterone Drug: placebo-recFSH (follitropin beta) Drug: placebo-corifollitropin alfa Biological: open-label recFSH (follitropin beta)

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

No text entered.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Women/Expectant Mothers	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day by intramuscular [IM] injection), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Women/Expectant Mothers	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including the Day of hCG administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.
Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	This group includes fetuses of expectant mothers who were administered corifollitropin alfa in base study P05690 (NCT00702845). The fetuses were present at 10 weeks after embryo transfer (ET) in the base study, and expectant mothers were eligible for enrollment in follow up study P05710.
recFSH 150 IU Fetuses at 10 Weeks After ET	This group includes fetuses of expectant mothers who were administered recFSH on base study P05690 (NCT00702845). The fetuses were present at 10 weeks after ET in the base study, and expectant mothers were eligible for enrollment in follow up study P05710.

Participant Flow for 3 periods

Period 1: Base Study P05690 (NCT00702845)

	Corifollitropin Alfa 100 µg Women/Expectant Mothers	recFSH 150 IU Women/Expectant Mothers	Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	recFSH 150 IU Fetuses at 10 Weeks After ET
STARTED	**268**	**128**	**0**	**0**
COMPLETED	**246** [1]	**121** [1]	**0**	**0**
NOT COMPLETED	**22**	**7**	**0**	**0**

[1] To complete study, participants from the base study P05690 (NCT00702845) had embryos transferred.

Period 2: Expectant Mother Follow-up

	Corifollitropin Alfa 100 µg Women/Expectant Mothers	recFSH 150 IU Women/Expectant Mothers	Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	recFSH 150 IU Fetuses at 10 Weeks After ET
STARTED	**68**	**45**	**0**	**0**
COMPLETED	**61** [1]	**45** [1]	**0**	**0**

NOT COMPLETED	**7**	**0**	**0**	**0**

[1] To complete the study, participants must have completed a follow-up visit at 4-12 weeks postpartum.

Period 3: Fetuses/Infant Follow-up

	Corifollitropin Alfa 100 µg Women/Expectant Mothers	recFSH 150 IU Women/Expectant Mothers	Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	recFSH 150 IU Fetuses at 10 Weeks After ET
STARTED	**0**	**0**	**88**	**55**
Live Born Infants	**0**	**0**	**80** [1]	**55** [2]
COMPLETED	**0**	**0**	**78** [3]	**55** [3]
NOT COMPLETED	**0**	**0**	**10**	**0**

[1] Infants born to eligible mothers were followed for safety and efficacy
[2] Infants born to eligible mothers were followed for safety and efficacy.
[3] To complete the study, infants must have completed a follow-up visit at 4-12 weeks postpartum.

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.
Individuals who participated in base study P05690 (NCT00702845) and received at least one dose of either corifollitropin alfa or recFSH, who had an ongoing pregnancy confirmed by ultrasound at least 10 weeks after ET in base study P05690 and were able and willing to give written informed consent.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Expectant Mothers	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Expectant Mothers	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including the Day of hCG administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.

Total	Total of all reporting groups

Baseline Measures

	Corifollitropin Alfa 100 µg Expectant Mothers	recFSH 150 IU Expectant Mothers	Total
Number of Participants [units: participants]	68	45	113
Age [units: Years] Mean (Standard Deviation)	30.5 (3.3)	31.3 (3.1)	30.8 (3.2)
Gender [units: Participants]			
Female	68	45	113
Male	0	0	0

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Women With ≥1 Live Born Infant During Follow-up (Take-Home Baby Rate) [Time Frame: From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)]

Measure Type	Primary
Measure Title	Percentage of Women With ≥1 Live Born Infant During Follow-up (Take-Home Baby Rate)
Measure Description	The Take-Home Baby Rate was defined as the number of participants with an ongoing pregnancy in base study P05690 with at least one live born infant during follow up relative to the number of participants treated in base study.
Time Frame	From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)
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.
Intent-to-Treat (ITT) group from base study P05690 (NCT00702845), which consisted of randomized participants who were treated with corifollitropin alfa or recFSH.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Women	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Women	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including the Day of hCG

	administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.

Measured Values

	Corifollitropin Alfa 100 µg Women	recFSH 150 IU Women
Number of Participants Analyzed [units: participants]	**268**	**128**
Percentage of Women With ≥1 Live Born Infant During Follow-up (Take-Home Baby Rate) [units: Percentage of participants]	**23.5**	**34.4**

No statistical analysis provided for Percentage of Women With ≥1 Live Born Infant During Follow-up (Take-Home Baby Rate)

2. Primary: Number of Expectant Mothers Experiencing Adverse Events (AEs) [Time Frame: From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)]

Measure Type	Primary
Measure Title	Number of Expectant Mothers Experiencing Adverse Events (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	From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)
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.
Follow-up safety analysis was performed on expectant mothers who received corifollitropin alfa or recFSH on base study P05690 (NCT00702845) and who enrolled on the follow-up study.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Expectant Mothers	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Expectant Mothers	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards,

	up to and including the Day of hCG administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.

Measured Values

	Corifollitropin Alfa 100 µg Expectant Mothers	recFSH 150 IU Expectant Mothers
Number of Participants Analyzed [units: participants]	**68**	**45**
Number of Expectant Mothers Experiencing Adverse Events (AEs) [units: Participants]	**48**	**35**

No statistical analysis provided for Number of Expectant Mothers Experiencing Adverse Events (AEs)

3. Primary: Number of Expectant Mothers Experiencing Serious AEs (SAEs) [Time Frame: From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)]

Measure Type	Primary
Measure Title	Number of Expectant Mothers Experiencing 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.
Time Frame	From approximately 10 weeks after ET in base study P05690 up to birth of infant (up to approximately 6 months)
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.
Follow-up safety analysis was performed on expectant mothers who received corifollitropin alfa or recFSH on base study P05690 (NCT00702845) and who enrolled on the follow-up study.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Expectant Mothers	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day by intramuscular [IM] injection), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Expectant Mothers	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards,

	up to and including the Day of hCG administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.

Measured Values

	Corifollitropin Alfa 100 µg Expectant Mothers	recFSH 150 IU Expectant Mothers
Number of Participants Analyzed [units: participants]	**68**	**45**
Number of Expectant Mothers Experiencing Serious AEs (SAEs) [units: Participants]	**38**	**21**

No statistical analysis provided for Number of Expectant Mothers Experiencing Serious AEs (SAEs)

4. Primary: Number of Infants Experiencing AEs [Time Frame: Up to 12 weeks after birth]

Measure Type	Primary
Measure Title	Number of Infants Experiencing 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 can 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 12 weeks after birth
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.
Follow-up safety analysis was performed on live born infants delivered by expectant mothers who received corifollitropin alfa or recFSH on base study P05690 (NCT00702845) and who enrolled on the follow-up study.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Follow-Up Infants	Infants that were born to eligible mothers who received SC corifollitropin alfa plus hCG on base study P05690 (NCT00702845) were followed for safety and efficacy on the current follow-up study (P05710) according to standard practice.
recFSH 150 IU Follow-Up Infants	Infants that were born to eligible mothers who received SC recFSH plus hCG on base study P05690 (NCT00702845) were followed for safety and efficacy on the current follow-up study (P05710) according to standard practice.

Measured Values

	Corifollitropin Alfa 100 µg Follow-Up Infants	recFSH 150 IU Follow-Up Infants
Number of Participants Analyzed	**80**	**55**

[units: participants]		
Number of Infants Experiencing AEs **[units: Live born infants]**	**37**	**27**

No statistical analysis provided for Number of Infants Experiencing AEs

5. Primary: Number of Infants Experiencing SAEs [Time Frame: Up to 12 weeks after birth]

Measure Type	Primary
Measure Title	Number of Infants Experiencing 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.
Time Frame	Up to 12 weeks after birth
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.
Follow-up safety analysis was performed on live born infants delivered by expectant mothers who received corifollitropin alfa or recFSH on base study P05690 (NCT00702845) and who enrolled on the follow-up study.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Follow-Up Infants	Infants that were born to eligible mothers who received SC corifollitropin alfa plus hCG on base study P05690 (NCT00702845) were followed for safety and efficacy on the current follow-up study (P05710) according to standard practice.
recFSH 150 IU Follow-Up Infants	Infants that were born to eligible mothers who received SC recFSH plus hCG on base study P05690 (NCT00702845) were followed for safety and efficacy on the current follow-up study (P05710) according to standard practice.

Measured Values

	Corifollitropin Alfa 100 µg Follow-Up Infants	**recFSH 150 IU Follow-Up Infants**
Number of Participants Analyzed [units: participants]	**80**	**55**
Number of Infants Experiencing SAEs **[units: Live born infants]**	**30**	**16**

No statistical analysis provided for Number of Infants Experiencing SAEs

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From approximately 10 weeks after ET in base study P05690 (NCT00702845) up to 12 weeks after birth in current follow-up study (up to approximately 9 months)
Additional Description	No text entered.

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Expectant Mothers	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day by intramuscular [IM] injection), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Expectant Mothers	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including the Day of hCG administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.
Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	This group includes fetuses of expectant mothers who were administered corifollitropin alfa in base study P05690 (NCT00702845). The fetuses were present at 10 weeks after embryo transfer (ET) in the base study, and expectant mothers were eligible for enrollment in follow up study P05710.
recFSH 150 IU Fetuses at 10 Weeks After ET	This group includes fetuses of expectant mothers who were administered recFSH on base study P05690 (NCT00702845). The fetuses were present at 10 weeks after ET in the base study, and expectant mothers were eligible for enrollment in follow up study P05710.

Serious Adverse Events

	Corifollitropin Alfa 100 µg Expectant Mothers	recFSH 150 IU Expectant Mothers	Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	recFSH 150 IU Fetuses at 10 Weeks After ET
Total, serious adverse events				
# participants affected / at risk	**38/68 (55.88%)**	**21/45 (46.67%)**	**31/88 (35.23%)**	**16/55 (29.09%)**
Blood and lymphatic system disorders				
Thrombocytopenia neonatal † [1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**1/55 (1.82%)**
# events	**0**	**0**	**1**	**1**
Cardiac disorders				

Mitral valve prolapse † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Bradycardia foetal † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Tachycardia foetal † 1				
# participants affected / at risk	**0/68 (0.00%)**	**1/45 (2.22%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**0**	**1**	**0**	**0**
Pulmonary valve stenosis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Congenital, familial and genetic disorders				
Aplasia cutis congenita † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Atrial septal defect † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**3/55 (5.45%)**
# events	**0**	**0**	**0**	**3**
Congenital infection † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Congenital pneumonia † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**2/88 (2.27%)**	**0/55 (0.00%)**
# events	**0**	**0**	**2**	**0**
Congenital pulmonary artery anomaly † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Congenital pyelocaliectasis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**2/55 (3.64%)**
# events	**0**	**0**	**0**	**2**
Congenital syphilis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**

# events	0	0	1	0
Haemangioma congenital † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0
Patent ductus arteriosus † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	2/88 (2.27%)	2/55 (3.64%)
# events	0	0	2	2
Pulmonary artery stenosis congenital † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	0/88 (0.00%)	1/55 (1.82%)
# events	0	0	0	1
Pyloric stenosis † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	0/88 (0.00%)	1/55 (1.82%)
# events	0	0	0	1
Renal dysplasia † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0
Ventricular septal defect † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	0/88 (0.00%)	1/55 (1.82%)
# events	0	0	0	1
Eye disorders				
Retinopathy of prematurity † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	0/88 (0.00%)	1/55 (1.82%)
# events	0	0	0	1
Gastrointestinal disorders				
Dysphagia † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0
General disorders				
Fever neonatal † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0
Oedema neonatal † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0

Hepatobiliary disorders				
Liver disorder † 1				
# participants affected / at risk	**0/68 (0.00%)**	**1/45 (2.22%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**0**	**1**	**0**	**0**
Hyperbilirubinaemia neonatal † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**8/88 (9.09%)**	**6/55 (10.91%)**
# events	**0**	**0**	**8**	**6**
Neonatal cholestasis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Infections and infestations				
Intrauterine infection † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Tuberculosis † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Urinary tract infection bacterial † 1				
# participants affected / at risk	**0/68 (0.00%)**	**1/45 (2.22%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**0**	**1**	**0**	**0**
Oral fungal infection † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Pneumonia chlamydial † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Pneumonia viral † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Pulmonary sepsis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Sepsis neonatal † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**

Staphylococcal infection † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Injury, poisoning and procedural complications				
Transfusion-related acute lung injury † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Investigations				
Cardiac murmur functional † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Metabolism and nutrition disorders				
Dehydration † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Hypoglycaemia neonatal † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Hypokalaemia † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Metabolic acidosis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Metabolic alkalosis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Neonatal hyponatraemia † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Nervous system disorders				
Cerebral infarction foetal † 1				
# participants				

affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0
Intraventricular haemorrhage neonatal † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0
Pregnancy, puerperium and perinatal conditions				
Abortion missed † 1				
# participants affected / at risk	1/68 (1.47%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	0	0	0
Abortion spontaneous † 1				
# participants affected / at risk	1/68 (1.47%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	0	0	0
Antepartum haemorrhage † 1				
# participants affected / at risk	1/68 (1.47%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	2	0	0
Arrested labour † 1				
# participants affected / at risk	0/68 (0.00%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	0	1	0	0
Breech presentation † 1				
# participants affected / at risk	2/68 (2.94%)	2/45 (4.44%)	0/88 (0.00%)	0/55 (0.00%)
# events	2	2	0	0
Cephalo-pelvic disproportion † 1				
# participants affected / at risk	2/68 (2.94%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	2	1	0	0
Cervical incompetence † 1				
# participants affected / at risk	3/68 (4.41%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	3	0	0	0
Cervix dystocia † 1				
# participants affected / at risk	1/68 (1.47%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	0	0	0
Chorioamnionitis † 1				
# participants affected / at risk	1/68 (1.47%)	2/45 (4.44%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	2	0	0

Complication of delivery † 1				
# participants affected / at risk	**0/68 (0.00%)**	**1/45 (2.22%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**0**	**1**	**0**	**0**
Failed induction of labour † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Foetal distress syndrome † 1				
# participants affected / at risk	**2/68 (2.94%)**	**1/45 (2.22%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**2**	**1**	**0**	**0**
Foetal hypokinesia † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Foetal macrosomia † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Foetal malposition † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Foetal malpresentation † 1				
# participants affected / at risk	**3/68 (4.41%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**3**	**0**	**0**	**0**
Intra-uterine death † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Multiple pregnancy † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Oligohydramnios † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Placenta praevia † 1				
# participants affected / at risk	**2/68 (2.94%)**	**6/45 (13.33%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**2**	**6**	**0**	**0**
Pre-eclampsia † 1				
# participants				

affected / at risk	0/68 (0.00%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	0	1	0	0
Pregnancy induced hypertension † 1				
# participants affected / at risk	0/68 (0.00%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	0	1	0	0
Premature labour † 1				
# participants affected / at risk	14/68 (20.59%)	5/45 (11.11%)	0/88 (0.00%)	0/55 (0.00%)
# events	14	5	0	0
Premature rupture of membranes † 1				
# participants affected / at risk	7/68 (10.29%)	4/45 (8.89%)	0/88 (0.00%)	0/55 (0.00%)
# events	7	4	0	0
Premature separation of placenta † 1				
# participants affected / at risk	0/68 (0.00%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	0	1	0	0
Prolonged labour † 1				
# participants affected / at risk	1/68 (1.47%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	0	0	0
Stillbirth † 1				
# participants affected / at risk	3/68 (4.41%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	4	0	0	0
Threatened labour † 1				
# participants affected / at risk	5/68 (7.35%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	5	1	0	0
Twin pregnancy † 1				
# participants affected / at risk	9/68 (13.24%)	3/45 (6.67%)	0/88 (0.00%)	0/55 (0.00%)
# events	9	3	0	0
Uterine contractions during pregnancy † 1				
# participants affected / at risk	1/68 (1.47%)	1/45 (2.22%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	2	0	0
Uterine hypotonus † 1				
# participants affected / at risk	1/68 (1.47%)	0/45 (0.00%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	0	0	0
Hypothermia neonatal † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	1/88 (1.14%)	0/55 (0.00%)
# events	0	0	1	0

Jaundice neonatal † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**3/88 (3.41%)**	**5/55 (9.09%)**
# events	**0**	**0**	**3**	**5**
Premature baby † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**20/88 (22.73%)**	**9/55 (16.36%)**
# events	**0**	**0**	**20**	**9**
Small for dates baby † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**4/88 (4.55%)**	**2/55 (3.64%)**
# events	**0**	**0**	**4**	**2**
Hydrops foetalis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Renal and urinary disorders				
Nephrocalcinosis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Pyelocaliectasis † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Reproductive system and breast disorders				
Ovarian cyst † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Respiratory, thoracic and mediastinal disorders				
Acute respiratory distress syndrome † 1				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Bronchopulmonary dysplasia † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Hypoventilation neonatal † 1				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**2/88 (2.27%)**	**0/55 (0.00%)**
# events	**0**	**0**	**2**	**0**
†				

Infantile apnoeic attack [1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**2/55 (3.64%)**
# events	**0**	**0**	**0**	**2**
Neonatal respiratory distress syndrome [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**4/88 (4.55%)**	**3/55 (5.45%)**
# events	**0**	**0**	**4**	**3**
Pneumothorax [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**2/88 (2.27%)**	**0/55 (0.00%)**
# events	**0**	**0**	**2**	**0**
Pulmonary hypertensive crisis [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Respiratory disorder neonatal [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**1/55 (1.82%)**
# events	**0**	**0**	**0**	**1**
Transient tachypnoea of the newborn [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**5/88 (5.68%)**	**3/55 (5.45%)**
# events	**0**	**0**	**5**	**3**
Wheezing [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**
Surgical and medical procedures				
Cervix cerclage procedure [† 1]				
# participants affected / at risk	**1/68 (1.47%)**	**0/45 (0.00%)**	**0/88 (0.00%)**	**0/55 (0.00%)**
# events	**1**	**0**	**0**	**0**
Vascular disorders				
Neonatal hypotension [† 1]				
# participants affected / at risk	**0/68 (0.00%)**	**0/45 (0.00%)**	**1/88 (1.14%)**	**0/55 (0.00%)**
# events	**0**	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	From approximately 10 weeks after ET in base study P05690 (NCT00702845) up to 12 weeks after birth in current follow-up study (up to approximately 9 months)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Corifollitropin Alfa 100 µg Expectant Mothers	Participants in base study P05690 received single SC injection of corifollitropin alfa 100 µg (Org 36286) on Day 2 or 3 of menstrual cycle and daily placebo recFSH injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including Day of hCG administration. Participants also received GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including Day of hCG (10,000 or 5,000 IU/USP); and progesterone (at least 600 mg/day vaginally or 50 mg/day by intramuscular [IM] injection), starting on day of OPU and continuing at least 6 weeks or up to menses. Eligible participants from base study were enrolled in follow up study P05710, but no study treatments were given.
recFSH 150 IU Expectant Mothers	Participants in the reference group in base study P05690 received a single SC injection of placebo-corifollitropin alfa administered on Day 2 or 3 of the menstrual cycle and daily SC recFSH 150 IU injections (7 total) from Stimulation Day 1 up to and including Stimulation Day 7. Participants also received open-label recFSH (up to 200 IU/day) from Stimulation Day 8 onwards, up to and including the Day of hCG administration. Participants also received the GnRH antagonist ganirelix (0.25 mg) once daily SC starting on Stimulation Day 5 up to and including the Day of hCG (10,000 or 5,000 IU/USP). Participants also received progesterone (at least 600 mg/day vaginally or 50 mg/day IM), starting on the Day of OPU and continuing for at least 6 weeks or up to menses. Eligible participants from the base study were enrolled in follow up study P05710, but no study treatments were given.
Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	This group includes fetuses of expectant mothers who were administered corifollitropin alfa in base study P05690 (NCT00702845). The fetuses were present at 10 weeks after embryo transfer (ET) in the base study, and expectant mothers were eligible for enrollment in follow up study P05710.
recFSH 150 IU Fetuses at 10 Weeks After ET	This group includes fetuses of expectant mothers who were administered recFSH on base study P05690 (NCT00702845). The fetuses were present at 10 weeks after ET in the base study, and expectant mothers were eligible for enrollment in follow up study P05710.

Other Adverse Events

	Corifollitropin Alfa 100 µg Expectant Mothers	recFSH 150 IU Expectant Mothers	Corifollitropin Alfa 100 µg Fetuses at 10 Weeks After ET	recFSH 150 IU Fetuses at 10 Weeks After ET
Total, other (not including serious) adverse events				
# participants affected / at risk	**13/68 (19.12%)**	**17/45 (37.78%)**	**9/88 (10.23%)**	**5/55 (9.09%)**
Blood and lymphatic system disorders				
Anaemia † [1]				

# participants affected / at risk	5/68 (7.35%)	6/45 (13.33%)	0/88 (0.00%)	0/55 (0.00%)
# events	5	6	0	0
General disorders				
Pyrexia † 1				
# participants affected / at risk	4/68 (5.88%)	0/45 (0.00%)	0/88 (0.00%)	2/55 (3.64%)
# events	4	0	0	2
Hepatobiliary disorders				
Hyperbilirubinaemia neonatal † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	5/88 (5.68%)	0/55 (0.00%)
# events	0	0	5	0
Pregnancy, puerperium and perinatal conditions				
Abnormal labour † 1				
# participants affected / at risk	0/68 (0.00%)	3/45 (6.67%)	0/88 (0.00%)	0/55 (0.00%)
# events	0	3	0	0
Antepartum haemorrhage † 1				
# participants affected / at risk	3/68 (4.41%)	4/45 (8.89%)	0/88 (0.00%)	0/55 (0.00%)
# events	3	4	0	0
Placenta praevia † 1				
# participants affected / at risk	0/68 (0.00%)	3/45 (6.67%)	0/88 (0.00%)	0/55 (0.00%)
# events	0	3	0	0
Threatened labour † 1				
# participants affected / at risk	1/68 (1.47%)	4/45 (8.89%)	0/88 (0.00%)	0/55 (0.00%)
# events	1	4	0	0
Jaundice neonatal † 1				
# participants affected / at risk	0/68 (0.00%)	0/45 (0.00%)	4/88 (4.55%)	3/55 (5.45%)
# events	0	0	6	3
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	5/68 (7.35%)	0/45 (0.00%)	0/88 (0.00%)	2/55 (3.64%)
# events	5	0	0	2

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

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:** The Sponsor recognizes the right of the investigator(s) to publish, but all publications must be based on data validated and released by the Sponsor. Any such scientific paper, presentation, or other communication concerning the clinical trial described in this protocol will first be submitted to Sponsor, at least six weeks ahead of estimated publication or presentation, for written consent, which shall not be withheld unreasonably.

Results Point of Contact:

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

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

Bonduelle M, Mannaerts B, Leader A, Bergh C, Passier D, Devroey P. Prospective follow-up of 838 fetuses conceived after ovarian stimulation with corifollitropin alfa: comparative and overall neonatal outcome. Hum Reprod. 2012 Jul;27(7):2177-85. doi: 10.1093/humrep/des156. Epub 2012 May 15.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00702624 History of Changes
Other Study ID Numbers:	P05710 2006-003812-23 (EudraCT Number) 107014 (Other Identifier: Organon) MK-8962-003 (Other Identifier: Merck)
Study First Received:	June 18, 2008
Results First Received:	April 13, 2015
Last Updated:	December 11, 2015
Health Authority:	Austria: Federal Office for Safety in Health Care Czech Republic: State Institute for Drug Control Denmark: Danish Medicines Agency Spain: Ministry of Health and Consumption France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Sweden: Medical Products Agency

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