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Trial record **1 of 1** for: cs24 | ferring [Lead]

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Exploratory Study Assessing Synchronisation of Egg Sacs With Degarelix

This study has been completed.

Sponsor:
Ferring Pharmaceuticals

Information provided by:
Ferring Pharmaceuticals

ClinicalTrials.gov Identifier:
NCT00434122

First received: February 9, 2007
Last updated: May 18, 2011
Last verified: May 2011
History of Changes

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Results First Received: January 19, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Investigator); Primary Purpose: Prevention
Condition:	Infertility, Female
Interventions:	Drug: Degarelix mid-luteal, 2.5 mg Drug: Placebo

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
Degarelix Mid-luteal, 2.5 mg	Degarelix 2.5 mg will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 6. Placebo will be injected SC on Stimulation Day 1.
Placebo	Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak. Degarelix 2.5 mg will be injected SC on Stimulation Day 1 and Stimulation Day 6. or Placebo will be injected SC 7 days after LH peak and on Stimulation Day 1. Ganirelix 0.25 mg will be injected SC daily from Stimulation Day 6 until the last stimulation day.

Participant Flow: Overall Study

	Degarelix Mid-luteal, 2.5 mg	Placebo
STARTED	**42** [1]	**43** [1]
Intention-to-treat (ITT) Population	**39** [2]	**39** [2]
COMPLETED	**36**	**36**
NOT COMPLETED	**6**	**7**

Non-compliance with protocol	0	1
loss of subject contact	1	1
Personal reasons	1	1
Large follicle size	2	2
Low follicular response.	1	2
Travelling of subject.	1	0

[1] Randomised
[2] All randomised and exposed subjects not withdrawn before Stimulation Day 1.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Degarelix Mid-luteal, 2.5 mg	Degarelix 2.5 mg will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 6. Placebo will be injected SC on Stimulation Day 1.
Placebo	Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak. Degarelix 2.5 mg will be injected SC on Stimulation Day 1 and Stimulation Day 6. or Placebo will be injected SC 7 days after LH peak and on Stimulation Day 1. Ganirelix 0.25 mg will be injected SC daily from Stimulation Day 6 until the last stimulation day.
Total	Total of all reporting groups

Baseline Measures

	Degarelix Mid-luteal, 2.5 mg	Placebo	Total
Number of Participants [units: participants]	**39**	**39**	**78**
Age [1] [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**39**	**39**	**78**
>=65 years	**0**	**0**	**0**
Age [2] [units: years] Mean ± Standard Deviation	**28.9 ± 4.1**	**28.0 ± 3.9**	**28.4 ± 4.0**
Gender [2] [units: participants]			
Female	**39**	**39**	**78**
Male	**0**	**0**	**0**
Region of Enrollment [2] [units: participants]			
Czech Republic	**7**	**7**	**14**
Spain	**27**	**26**	**53**
Belgium	**5**	**6**	**11**

[1] Intention-to-treat (ITT) population
[2] ITT population

Outcome Measures

Hide All Outcome Measures

1. Primary: Coefficient of Variation of Follicular Sizes on Stimulation Day 1 (Follicles ≥ 2 mm) [Time Frame: Stimulation Day 1]

Measure Type	Primary
Measure Title	Coefficient of Variation of Follicular Sizes on Stimulation Day 1 (Follicles ≥ 2 mm)
Measure Description	Explanation of the term "coefficient of variation": The coefficient of variation is a normalized measure of dispersion of a probability distribution.
Time Frame	Stimulation Day 1
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Degarelix Mid-luteal, 2.5 mg	Degarelix 2.5 mg will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 6. Placebo will be injected SC on Stimulation Day 1.
Placebo	Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak. Degarelix 2.5 mg will be injected SC on Stimulation Day 1 and Stimulation Day 6. or Placebo will be injected SC 7 days after LH peak and on Stimulation Day 1. Ganirelix 0.25 mg will be injected SC daily from Stimulation Day 6 until the last stimulation day.

Measured Values

	Degarelix Mid-luteal, 2.5 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**39**	**39**
Coefficient of Variation of Follicular Sizes on Stimulation Day 1 (Follicles ≥ 2 mm) [units: Percentage] Mean ± Standard Deviation	**36.7 ± 5.6**	**39.2 ± 9.5**

No statistical analysis provided for Coefficient of Variation of Follicular Sizes on Stimulation Day 1 (Follicles ≥ 2 mm)

2. Secondary: Frequency of Oocyte Donors With Adequate Secretory Transformation at the Endometrial Histology Evaluation 7 Days After Injection With Human Chorionic Gonadotrophin (hCG) [Time Frame: 7 days after hCG injection]

Measure Type	Secondary
Measure Title	Frequency of Oocyte Donors With Adequate Secretory Transformation at the Endometrial Histology Evaluation 7 Days After Injection With Human Chorionic Gonadotrophin (hCG)
Measure Description	An adequate secretory endometrium 7 days after hCG injection was defined as secretory in the histological classification and with endometrial dating corresponding to the expected cycle day ±1 day.
Time Frame	7 days after hCG injection
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.
Subjects with evaluable endometrial biopsies 7 days after injection with hCG.

Reporting Groups

	Description

Degarelix Mid-luteal, 2.5 mg	Degarelix 2.5 mg will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 6. Placebo will be injected SC on Stimulation Day 1.
Degarelix Follicular, 2.5 mg	Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak. Degarelix 2.5 mg will be injected SC on Stimulation Day 1 and Stimulation Day 6
Ganirelix, 0.25 mg	Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 1. Ganirelix 0.25 mg will be injected SC daily from Stimulation Day 6 until the last stimulation day.

Measured Values

	Degarelix Mid-luteal, 2.5 mg	Degarelix Follicular, 2.5 mg	Ganirelix, 0.25 mg
Number of Participants Analyzed [units: participants]	**32**	**14**	**16**
Frequency of Oocyte Donors With Adequate Secretory Transformation at the Endometrial Histology Evaluation 7 Days After Injection With Human Chorionic Gonadotrophin (hCG) [units: Participants]	**31**	**11**	**14**

No statistical analysis provided for Frequency of Oocyte Donors With Adequate Secretory Transformation at the Endometrial Histology Evaluation 7 Days After Injection With Human Chorionic Gonadotrophin (hCG)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From signed informed consent till end-of-trial visit (approximately 12 +/- 2 weeks after oocyte retrieval)
Additional Description	Evaluated at each trial visit

Reporting Groups

	Description
Degarelix, 2.5 mg	Combination of these two groups: Degarelix Mid-luteal 2.5 mg and Degarelix Follicular 2.5 mg. Degarelix Mid-luteal, 2.5 mg: Degarelix 2.5 mg will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 6. Placebo will be injected SC on Stimulation Day 1. Degarelix Follicular, 2.5 mg: Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak. Degarelix 2.5 mg will be injected SC on Stimulation Day 1 and Stimulation Day 6.
Ganirelix, 0.25 mg	Placebo will be injected SC 7 days after LH peak and on Stimulation Day 1. Ganirelix 0.25 mg will be injected SC daily from Stimulation Day 6 until the last stimulation day.

Serious Adverse Events

	Degarelix, 2.5 mg	Ganirelix, 0.25 mg
Total, serious adverse events		
# participants affected / at risk	**1/63 (1.59%)**	**0/22 (0.00%)**
Infections and infestations		
Cellulitis † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/22 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	From signed informed consent till end-of-trial visit (approximately 12 +/- 2 weeks after oocyte retrieval)
Additional Description	Evaluated at each trial visit

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Degarelix, 2.5 mg	Combination of these two groups: Degarelix Mid-luteal 2.5 mg and Degarelix Follicular 2.5 mg. Degarelix Mid-luteal, 2.5 mg: Degarelix 2.5 mg will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak and on Stimulation Day 6. Placebo will be injected SC on Stimulation Day 1. Degarelix Follicular, 2.5 mg: Placebo will be injected subcutaneously (SC) 7 days after luteinizing hormone (LH) peak. Degarelix 2.5 mg will be injected SC on Stimulation Day 1 and Stimulation Day 6.
Ganirelix, 0.25 mg	Placebo will be injected SC 7 days after LH peak and on Stimulation Day 1. Ganirelix 0.25 mg will be injected SC daily from Stimulation Day 6 until the last stimulation day.

Other Adverse Events

	Degarelix, 2.5 mg	Ganirelix, 0.25 mg
Total, other (not including serious) adverse events		
# participants affected / at risk	**7/63 (11.11%)**	**4/22 (18.18%)**
General disorders		
Injection site erythema †1		
# participants affected / at risk	**3/63 (4.76%)**	**0/22 (0.00%)**
# events	**3**	**0**
Immune system disorders		
Allergy to arthropod bite †1		
# participants affected / at risk	**0/63 (0.00%)**	**1/22 (4.55%)**
# events	**0**	**1**
Psychiatric disorders		
Mood swings †1		
# participants affected / at risk	**3/63 (4.76%)**	**0/22 (0.00%)**
# events	**3**	**0**
Reproductive system and breast disorders		
Menstruation delayed †1		
# participants affected / at risk	**1/63 (1.59%)**	**2/22 (9.09%)**
# events	**1**	**2**
Uterine polyp †1		
# participants affected / at risk	**0/63 (0.00%)**	**1/22 (4.55%)**
# events	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.0

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 only disclosure restiction on the PI is that the sponsor can review the draft manuscript prior to publication and can request delay of publication where any contents are deemed patentable by the sponsor or confidential to the sponsor. Comments will be given within four weeks from receipt of the draft manuscript.

Results Point of Contact:

Name/Title: Ferring Pharmaceuticals
Organization: Clinical Development Support
e-mail: DK0-Disclosure@ferring.com

No publications provided by Ferring Pharmaceuticals

Publications automatically indexed to this study:

García-Velasco JA, Kupesic S, Pellicer A, Bourgain C, Simón C, Mrazek M, Devroey P, Arce JC. Follicular and endocrine profiles associated with different GnRH-antagonist regimens: a randomized controlled trial. Reprod Biomed Online. 2012 Feb;24(2):153-62. doi: 10.1016/j.rbmo.2011.10.016. Epub 2011 Nov 4.

Responsible Party:	Clinical Development Support, Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00434122 History of Changes
Other Study ID Numbers:	FE200486 **CS24**
Study First Received:	February 9, 2007
Results First Received:	January 19, 2009
Last Updated:	May 18, 2011
Health Authority:	Spain: Spanish Agency of Medicines Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment Czech Republic: State Institute for Drug Control