ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 03/12/2015

An Extension Study Evaluating the Long-Term Safety and Tolerability of Degarelix One-Month Depots in Prostate Cancer

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by (Responsible Party):	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00215683

Purpose

This was an extension study for the study FE200486 CS12 (NCT00819156). Each participant was to be treated until he was discontinued or withdrawn from the study, or a marketing authorization for degarelix had been obtained.

The study was terminated when all ongoing participants had been treated for at least 5 years (including one year in the main study).

Condition	Intervention	Phase
Prostate Cancer	Drug: Degarelix	Phase 2/ Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Non-Randomized, Safety/Efficacy Study
Official Title: An Open-Label, Multi-Centre, Extension Study Evaluating the Long-Term Safety and Tolerability of Degarelix One-Month Depots in Patients With Prostate Cancer.

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Participants With Markedly Abnormal Change in Vital Signs and Body Weight [Time Frame: 5 years] [Designated as safety issue: No]

Vital signs and body weight included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight at the end of trial as compared to baseline. The table presents the number of participants in each group with normal baseline and markedly abnormal value post-baseline.

- Liver Function Tests [Time Frame: 5 years] [Designated as safety issue: No]
  The figures present the number of participants who had abnormal (defined as above upper limit of normal range (ULN)) alanine aminotransferase (ALT) levels, aspartate aminotransferase levels, and bilirubin levels plus the number of participants who had ALT increases >3x ULN and ALT increases >3x ULN with concurrently increased bilirubin >1.5 ULN.

Enrollment: 137
Study Start Date: February 2005
Primary Completion Date: October 2009
Study Completion Date: November 2009

Arms	Assigned Interventions
Experimental: Degarelix 80 mg Participants who completed the CS12 study in the Degarelix 80 mg arm continued that dose into the CS12A extension study. After a protocol amendment in January 2006 all study participants were treated with 160 mg (40 mg/mL).	Drug: Degarelix Drug supplied as a powder to be dissolved in the solvent for solution for injection. Degarelix given by subcutaneous injection every 28 days until the end of the study. Other Names: Degarelix acetate FE200486
Experimental: Degarelix 120 mg Participants who completed the CS12 study in the Degarelix 120 mg arm continued that dose into the CS12A extension study. After a protocol amendment in January 2006 all study participants were treated with 160 mg (40 mg/mL).	Drug: Degarelix Drug supplied as a powder to be dissolved in the solvent for solution for injection. Degarelix given by subcutaneous injection every 28 days until the end of the study. Other Names: Degarelix acetate FE200486
Experimental: Degarelix 160 mg Participants who completed the CS12 study in the Degarelix 160 mg arm continued that dose into the CS12A extension study. After a protocol amendment in January 2006 all study participants were treated with 160 mg (40 mg/mL).	Drug: Degarelix Drug supplied as a powder to be dissolved in the solvent for solution for injection. Degarelix given by subcutaneous injection every 28 days until the end of the study. Other Names: Degarelix acetate FE200486

Detailed Description:

Participants who completed the main FE200486 CS12 study initially continued with the same dose in the FE200486 CS12A extension study. After a protocol amendment all study participants were treated with 160 mg (40 mg/mL).

The data include data from the participants who participated in both the main study (FE200486 CS12; NCT00819156) and the extension study FE200486 CS12A.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion criteria:

- Had given written consent before any study-related activity was performed (a study-related activity was defined as any procedure that would not have been performed during the normal management of the participant)
- Had completed the FE200486 CS12 study

Exclusion criterion:

- Had been withdrawn from the FE200486 CS12 study

Contacts and Locations

Locations
- Belgium
  - UCL Saint Luc
    - Bruxelles, Belgium
  - Hôpital Erasme
    - Bruxelles, Belgium
  - UZ Gent
    - Gent, Belgium
  - UZ Gasthuisberg, Urology Department
    - Leuven, Belgium
- Germany
  - Vivantes Klinikum am Urban, Klinik für Urologie
    - Berlin, Germany
  - University Hospital Dresden, Carl Gustav Carus, Klinik und Poliklinik für Urologie
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Russian Federation

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Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals
Study ID Numbers:	FE200486 CS12A
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP Russia: Ethics Committee Russia: FSI Scientific Center of Expertise of Medical Application Russia: Ministry of Health of the Russian Federation Romania: Ministry of Public Health Romania: National Authority for Scientific Research Romania: National Medicines Agency Romania: State Institute for Drug Control Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Germany: Ethics Commission Germany: Federal Institute for Drugs and Medical Devices South Africa: Department of Health South Africa: Human Research Ethics Committee South Africa: Medicines Control Council South Africa: National Health Research Ethics Council Hungary: National Institute of Pharmacy

Study Results

Participant Flow

Recruitment Details	Participants who completed the main FE200486 CS12 study were asked to continue into the FE200486 CS12A extension study.
Pre-Assignment Details	189 participants were randomized into the main study CS12 and 147 patients completed CS12. Of these, 137 participants were recruited into the extension study CS12A and 109 participants signed the informed consent for dose shift.

Reporting Groups

	Description
Degarelix 80 mg	Participants who completed the CS12 study in the Degarelix 80 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 120 mg	Participants who completed the CS12 study in the Degarelix 120 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 160 mg	Participants who completed the CS12 study in the Degarelix 160 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.

Overall Study

	Degarelix 80 mg	Degarelix 120 mg	Degarelix 160 mg
Started	45 [1]	48	44
Switched to 160 mg	32 [2]	41	36
Completed	16 [3]	22	12
Not Completed	29	26	32
Adverse Event	15	16	15
Lack of Efficacy	5	1	2
Lost to Follow-up	0	2	1
Withdrawal by Subject	9	4	13
Physician Decision	0	0	1
Difficult to attend visits	0	1	0
No study drug available	0	1	0
Intermittent therapy required	0	1	0

[1] Safety analysis set
[2] A protocol amendment changed the dosage to 160 mg (40 mg/mL) for all participants
[3] Participants ongoing at the time of study closure were considered to have completed the study

Baseline Characteristics

Reporting Groups

	Description
Degarelix 80 mg	Participants who completed the CS12 study in the Degarelix 80 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 120 mg	Participants who completed the CS12 study in the Degarelix 120 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 160 mg	Participants who completed the CS12 study in the Degarelix 160 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.

Baseline Measures

	Degarelix 80 mg	Degarelix 120 mg	Degarelix 160 mg	Total
Number of Participants	45	48	44	137
Age, Continuous [units: years] Mean (Standard Deviation)	71.0 (7.9)	70.8 (6.3)	72.4 (7.7)	71.4 (7.3)
Gender, Male/Female [units: participants]				
Female	0	0	0	0
Male	45	48	44	137
Race (NIH/OMB) [1] [units: participants]				
American Indian or Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	3	0	3
White	45	44	44	133
More than one race	0	0	0	0

	Degarelix 80 mg	Degarelix 120 mg	Degarelix 160 mg	Total
Unknown or Not Reported	0	0	0	0
Body Weight [1] [units: kilogram] Mean (Standard Deviation)	79.4 (15.9)	79.1 (13.2)	76.8 (12.4)	78.4 (13.9)
Body Mass Index [1] [units: kilogram per square meter] Mean (Standard Deviation)	26.4 (4.5)	26.4 (3.4)	25.7 (3.4)	26.2 (3.8)
Curative Intent [2] [units: participants]				
Yes	3	3	3	9
No	42	45	41	128
Gleason Score [3] [units: participants]				
2-4	10	11	5	26
5-6	18	22	16	56
7-10	17	15	22	54
Stage of Prostate Cancer [4] [units: participants]				
Localized	10	14	8	32
Locally advanced	16	15	18	49
Metastatic	5	7	6	18
Not classifiable	14	12	12	38
Time since Prostate Cancer Diagnosis [5] [units: days] Mean (Standard Deviation)	355 (645)	227 (590)	457 (1086)	343 (798)

[1] Safety analysis set

[2] Safety analysis set. A curative intent of Yes refers to participants who have been castrated via radical prostatectomy or radiotherapy.

[3] Safety analysis set. The Gleason score is a system of grading the aggressiveness of the prostate cancer and how fast it is likely to grow and spread. Scale is 2-10, with low numbers being the least aggressive and 10 being the most aggressive. Gleason score for one patient in 160 mg group was missing.

[4] Safety analysis set. Prostate cancer stage was classified to describe the extent of cancer. Localized refers to tumors without involvement of lymph nodes or metastasis. Advanced localized can be larger tumors that may involve the lymph nodes but no metastasis. Metastatic are more advanced cancers that are spreading beyond the original tumor.

[5] Safety analysis set.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Participants With Markedly Abnormal Change in Vital Signs and Body Weight
Measure Description	Vital signs and body weight included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight at the end of trial as compared to baseline. The table presents the number of participants in each group with normal baseline and markedly abnormal value post-baseline.
Time Frame	5 years
Safety Issue?	No

Analysis Population Description

The data include data from participants participating in both the main study (FE200486 CS12) and the extension study FE200486 CS12A.

Reporting Groups

	Description
Degarelix 80 mg	Participants who completed the CS12 study in the Degarelix 80 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 120 mg	Participants who completed the CS12 study in the Degarelix 120 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 160 mg	Participants who completed the CS12 study in the Degarelix 160 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.

Measured Values

	Degarelix 80 mg	Degarelix 120 mg	Degarelix 160 mg
Number of Participants Analyzed	45	48	44
Participants With Markedly Abnormal Change in Vital Signs and Body Weight [units: participants]			
Diastolic blood pressure <=50 and decrease >=15	3	5	10

	Degarelix 80 mg	Degarelix 120 mg	Degarelix 160 mg
Diastolic blood pressure >=105 and increase >=15	9	5	9
Systolic blood pressure <=90 and decrease >=20	1	2	2
Systolic blood pressure >=180 and increase >=20	4	9	8
Heart rate <=50 and decrease >=15	3	5	5
Heart rate >=120 and increase >=15	1	1	0
Body weight decrease of >=7 percent	4	10	8
Body weight increase of >=7 percent	18	19	14

2. Primary Outcome Measure:

Measure Title	Liver Function Tests
Measure Description	The figures present the number of participants who had abnormal (defined as above upper limit of normal range (ULN)) alanine aminotransferase (ALT) levels, aspartate aminotransferase levels, and bilirubin levels plus the number of participants who had ALT increases >3x ULN and ALT increases >3x ULN with concurrently increased bilirubin >1.5 ULN.
Time Frame	5 years
Safety Issue?	No

Analysis Population Description

The data include data from participants participating in both the main study (FE200486 CS12) and the extension study FE200486 CS12A.

Reporting Groups

	Description
Degarelix 80 mg	Participants who completed the CS12 study in the Degarelix 80 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 120 mg	Participants who completed the CS12 study in the Degarelix 120 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 160 mg	Participants who completed the CS12 study in the Degarelix 160 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.

Measured Values

	Degarelix 80 mg	Degarelix 120 mg	Degarelix 160 mg
Number of Participants Analyzed	45	48	44
Liver Function Tests [units: participants]			
Abnormal alanine aminotransferase (ALAT)	19	18	23
Abnormal aspartate aminotransferase	18	23	21
Abnormal bilirubin	8	11	3
ALAT >3x upper limit of normal (ULN)	3	3	3
ALAT >3x ULN, bilirubin >1.5x ULN	0	0	0

Reported Adverse Events

Time Frame	5 years
Additional Description	Each patient's condition was monitored throughout the trial from the time of signing the informed consent until the end of the follow-up period. The investigator was to record all adverse events (AEs) in the AE log of the patient's Case Report Form.

Reporting Groups

	Description
Degarelix 80 mg	Participants who completed the CS12 study in the Degarelix 80 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 120 mg	Participants who completed the CS12 study in the Degarelix 120 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.
Degarelix 160 mg	Participants who completed the CS12 study in the Degarelix 160 mg arm continued that dose into the CS12A extension study. A protocol amendment in January 2006 changed the dosage to 160 mg (40 mg/mL) for all study participants.

Serious Adverse Events

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	19/45 (42.22%)		20/48 (41.67%)		10/44 (22.73%)	
Blood and lymphatic system disorders						
Anaemia [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Cardiac disorders						
Acute myocardial infarction [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Angina pectoris [A] †	2/45 (4.44%)	2	0/48 (0%)	0	0/44 (0%)	0
Atrial fibrillation [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	0/44 (0%)	0
Atrioventricular block [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Atrioventricular block complete [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Cardiac failure [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Cardiac failure acute [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Cardiopulmonary failure [A] †	1/45 (2.22%)	1	0/48 (0%)	0	1/44 (2.27%)	1
Myocardial infarction [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Supraventricular tachycardia [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Tachyarrhythmia [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Ventricular tachycardia [A] †	1/45 (2.22%)	10	0/48 (0%)	0	1/44 (2.27%)	1
Eye disorders						
Corneal defect [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Neurotrophic keratopathy [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Ulcerative keratitis [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	8
Gastrointestinal disorders						

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Diarrhoea [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Gastroenteritis [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Gastrointestinal haemorrhage [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Ileus [A] †	0/45 (0%)	0	2/48 (4.17%)	2	0/44 (0%)	0
Inguinal hernia [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Peritonitis [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Subileus [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
General disorders						
Disease progression [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	0/44 (0%)	0
Oedema peripheral [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Hepatobiliary disorders						
Hepatic cirrhosis [A] †	0/45 (0%)	0	0/48 (0%)	0	0/44 (0%)	0
Hepatic failure [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Jaundice cholestatic [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Infections and infestations						
Appendicitis perforated [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Bronchitis [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Bronchopneumonia [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Gastroenteritis viral [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Pneumonia [A] †	0/45 (0%)	0	4/48 (8.33%)	5	1/44 (2.27%)	1
Sepsis [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Urinary tract infection [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Injury, poisoning and procedural complications						
Femoral neck fracture [A] †	2/45 (4.44%)	2	0/48 (0%)	0	0/44 (0%)	0
Spinal compression fracture [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	0/44 (0%)	0
Investigations						
Angiogram [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Blood potassium increased [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Metabolism and nutrition disorders						
Dehydration [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Diabetes mellitus inadequate control [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Musculoskeletal and connective tissue disorders						
Acoustic neuroma [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Arthralgia [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Back pain [A] †	2/45 (4.44%)	3	1/48 (2.08%)	1	0/44 (0%)	0
Groin pain [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Intravertebral disc compression [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Muscular weakness [A] †	0/45 (0%)	0	1/48 (2.08%)	2	0/44 (0%)	0
Pain in extremity [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Benign colonic neoplasm [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Brain neoplasm [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Bronchial carcinoma [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Carcinoma in situ of eye [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Colon cancer [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Colorectal cancer [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Lung neoplasm [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Lung neoplasm malignant [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Lymphangiosis carcinomatosa [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Metastases to bone [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	1/44 (2.27%)	1
Metastases to liver [A] †	2/45 (4.44%)	2	0/48 (0%)	0	0/44 (0%)	0
Metastasis [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Metastatic neoplasm [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Pancreatic carcinoma [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Paraparesis [A] †	0/45 (0%)	0	1/48 (2.08%)	2	0/44 (0%)	0
Post polio syndrome [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Renal cell carcinoma stage I [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Nervous system disorders						
Aphasia [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Cerebovascular accident [A] †	3/45 (6.67%)	3	2/48 (4.17%)	2	1/44 (2.27%)	1
Cerebral circulatory failure [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Cerebral infarction [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Monoplegia [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	2
Neuralgia [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Sciatica [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Spinal cord compression [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Transient ischaemic attack [A] †	1/45 (2.22%)	1	0/48 (0%)	0	1/44 (2.27%)	1
Psychiatric disorders						
Confusional state [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Depression [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Renal and urinary disorders						
Anuria [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Bladder neck obstruction [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Bladder obstruction [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Bladder tamponade [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Haematuria [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Hydronephrosis [A] †	2/45 (4.44%)	2	0/48 (0%)	0	0/44 (0%)	0
Renal failure [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Urethral obstruction [A] †	1/45 (2.22%)	1	1/48 (2.08%)	3	0/44 (0%)	0
Urinary retention [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	2/44 (4.55%)	2
Respiratory, thoracic and mediastinal disorders						
Chronic obstructive pulmonary disease [A] †	1/45 (2.22%)	1	0/48 (0%)	0	0/44 (0%)	0
Haemoptysis [A] †	0/45 (0%)	0	0/48 (0%)	0	1/44 (2.27%)	1
Pulmonary embolism [A] †	2/45 (4.44%)	2	0/48 (0%)	0	0/44 (0%)	0
Skin and subcutaneous tissue disorders						
Skin ulcer [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0
Vascular disorders						
Femoral artery occlusion [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Hypertension [A] †	0/45 (0%)	0	1/48 (2.08%)	1	1/44 (2.27%)	2
Lymphoedema [A] †	0/45 (0%)	0	1/48 (2.08%)	1	0/44 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	35/45 (77.78%)		41/48 (85.42%)		38/44 (86.36%)	
Blood and lymphatic system disorders						
Anaemia [A] †	3/45 (6.67%)	6	1/48 (2.08%)	1	2/44 (4.55%)	2
Cardiac disorders						
Atrial fibrillation [A] †	1/45 (2.22%)	1	4/48 (8.33%)	5	1/44 (2.27%)	1
Atrioventricular block first degree [A] †	3/45 (6.67%)	3	3/48 (6.25%)	3	0/44 (0%)	0
Bradycardia [A] †	0/45 (0%)	0	1/48 (2.08%)	1	2/44 (4.55%)	2
Myocardial ischaemia [A] †	2/45 (4.44%)	2	2/48 (4.17%)	2	2/44 (4.55%)	2
Ventricular extrasystoles [A] †	0/45 (0%)	0	4/48 (8.33%)	4	0/44 (0%)	0
Ear and labyrinth disorders						
Vertigo [A] †	0/45 (0%)	0	0/48 (0%)	0	2/44 (4.55%)	3
Eye disorders						
Cataract [A] †	2/45 (4.44%)	4	2/48 (4.17%)	4	3/44 (6.82%)	4
Gastrointestinal disorders						
Abdominal pain [A] †	2/45 (4.44%)	2	1/48 (2.08%)	1	2/44 (4.55%)	3

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Constipation [A] †	7/45 (15.56%)	9	2/48 (4.17%)	3	2/44 (4.55%)	2
Diarrhoea [A] †	3/45 (6.67%)	6	5/48 (10.42%)	5	6/44 (13.64%)	7
Dyspepsia [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	0/44 (0%)	0
Nausea [A] †	5/45 (11.11%)	7	1/48 (2.08%)	2	4/44 (9.09%)	4
General disorders						
Asthenia [A] †	4/45 (8.89%)	4	2/48 (4.17%)	2	2/44 (4.55%)	2
Chest pain [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	2/44 (4.55%)	2
Fatigue [A] †	6/45 (13.33%)	8	3/48 (6.25%)	7	6/44 (13.64%)	9
Hyperthermia [A] †	0/45 (0%)	0	1/48 (2.08%)	1	2/44 (4.55%)	2
Injection site erythema [A] †	3/45 (6.67%)	4	2/48 (4.17%)	4	9/44 (20.45%)	15
Injection site haematoma [A] †	1/45 (2.22%)	1	0/48 (0%)	0	2/44 (4.55%)	2
Injection site inflammation [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	4/44 (9.09%)	4
Injection site nodule [A] †	3/45 (6.67%)	7	5/48 (10.42%)	6	5/44 (11.36%)	5
Injection site pain [A] †	6/45 (13.33%)	28	11/48 (22.92%)	22	13/44 (29.55%)	48
Injection site reaction [A] †	0/45 (0%)	0	0/48 (0%)	0	3/44 (6.82%)	4
Injection site swelling [A] †	0/45 (0%)	0	4/48 (8.33%)	9	6/44 (13.64%)	13
Oedema peripheral [A] †	4/45 (8.89%)	6	4/48 (8.33%)	6	2/44 (4.55%)	4
Pyrexia [A] †	6/45 (13.33%)	7	3/48 (6.25%)	6	6/44 (13.64%)	11
Infections and infestations						
Bronchitis [A] †	4/45 (8.89%)	4	2/48 (4.17%)	2	5/44 (11.36%)	8
Gastroenteritis [A] †	2/45 (4.44%)	2	3/48 (6.25%)	3	2/44 (4.55%)	2

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Influenza [A] †	6/45 (13.33%)	8	9/48 (18.75%)	15	8/44 (18.18%)	9
Nasopharyngitis [A] †	2/45 (4.44%)	7	2/48 (4.17%)	4	4/44 (9.09%)	8
Pneumonia [A] †	3/45 (6.67%)	3	2/48 (4.17%)	3	3/44 (6.82%)	3
Rhinitis [A] †	1/45 (2.22%)	1	0/48 (0%)	0	4/44 (9.09%)	5
Upper respiratory tract infection [A] †	0/45 (0%)	0	4/48 (8.33%)	5	1/44 (2.27%)	1
Urinary tract infection [A] †	4/45 (8.89%)	6	6/48 (12.5%)	11	4/44 (9.09%)	4
Investigations						
Alanine aminotransferase increased [A] †	2/45 (4.44%)	2	3/48 (6.25%)	6	3/44 (6.82%)	5
Aspartate aminotransferase increased [A] †	2/45 (4.44%)	2	1/48 (2.08%)	4	2/44 (4.55%)	3
Blood alkaline phosphatase increased [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	5/44 (11.36%)	7
Blood creatinine increased [A] †	2/45 (4.44%)	3	1/48 (2.08%)	1	3/44 (6.82%)	3
Blood urea increased [A] †	2/45 (4.44%)	4	2/48 (4.17%)	2	5/44 (11.36%)	5
Gamma-glutamyltransferase increased [A] †	3/45 (6.67%)	3	2/48 (4.17%)	3	3/44 (6.82%)	5
Platelet count decreased [A] †	1/45 (2.22%)	1	0/48 (0%)	0	2/44 (4.55%)	3
Prostatic specific antigen increased [A] †	11/45 (24.44%)	12	8/48 (16.67%)	10	7/44 (15.91%)	9
Weight decreased [A] †	3/45 (6.67%)	3	7/48 (14.58%)	9	8/44 (18.18%)	8
Weight increased [A] †	7/45 (15.56%)	7	9/48 (18.75%)	10	7/44 (15.91%)	7
Metabolism and nutrition disorders						
Hypercholesterolaemia [A] †	2/45 (4.44%)	2	0/48 (0%)	0	2/44 (4.55%)	2
Hyperkalaemia [A] †	2/45 (4.44%)	2	0/48 (0%)	0	2/44 (4.55%)	2
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	3/45 (6.67%)	9	6/48 (12.5%)	8	9/44 (20.45%)	24

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Back pain [A] †	6/45 (13.33%)	9	7/48 (14.58%)	7	5/44 (11.36%)	5
Joint swelling [A] †	1/45 (2.22%)	2	1/48 (2.08%)	1	2/44 (4.55%)	2
Muscle spasms [A] †	3/45 (6.67%)	5	2/48 (4.17%)	2	3/44 (6.82%)	3
Muscular weakness [A] †	3/45 (6.67%)	4	1/48 (2.08%)	2	0/44 (0%)	0
Musculoskeletal pain [A] †	5/45 (11.11%)	7	1/48 (2.08%)	1	1/44 (2.27%)	1
Mylagia [A] †	1/45 (2.22%)	1	0/48 (0%)	0	4/44 (9.09%)	5
Osteoarthritis [A] †	2/45 (4.44%)	2	1/48 (2.08%)	1	3/44 (6.82%)	5
Pain in extremity [A] †	5/45 (11.11%)	7	3/48 (6.25%)	4	3/44 (6.82%)	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Basal cell carcinoma [A] †	0/45 (0%)	0	0/48 (0%)	0	2/44 (4.55%)	2
Metastases to bone [A] †	2/45 (4.44%)	2	1/48 (2.08%)	1	2/44 (4.55%)	2
Nervous system disorders						
Dizziness [A] †	1/45 (2.22%)	1	5/48 (10.42%)	8	3/44 (6.82%)	3
Headache [A] †	3/45 (6.67%)	3	0/48 (0%)	0	2/44 (4.55%)	4
Psychiatric disorders						
Anxiety [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	3/44 (6.82%)	3
Depression [A] †	2/45 (4.44%)	2	0/48 (0%)	0	3/44 (6.82%)	3
Insomnia [A] †	2/45 (4.44%)	2	4/48 (8.33%)	4	4/44 (9.09%)	5
Renal and urinary disorders						
Dysuria [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	0/44 (0%)	0
Haematuria [A] †	4/45 (8.89%)	4	0/48 (0%)	0	5/44 (11.36%)	7
Nocturia [A] †	3/45 (6.67%)	3	1/48 (2.08%)	1	1/44 (2.27%)	2

	Degarelix 80 mg		Degarelix 120 mg		Degarelix 160 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Pollakiuria [A] †	1/45 (2.22%)	1	1/48 (2.08%)	1	2/44 (4.55%)	2
Renal collic [A] †	1/45 (2.22%)	1	0/48 (0%)	0	2/44 (4.55%)	2
Urinary retention [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	1/44 (2.27%)	1
Reproductive system and breast disorders						
Dyspnoea [A] †	3/45 (6.67%)	3	3/48 (6.25%)	4	3/44 (6.82%)	4
Erectile dysfunction [A] †	3/45 (6.67%)	4	1/48 (2.08%)	1	3/44 (6.82%)	3
Gynaecomastia [A] †	3/45 (6.67%)	3	0/48 (0%)	0	1/44 (2.27%)	1
Prostatism [A] †	3/45 (6.67%)	4	0/48 (0%)	0	2/44 (4.55%)	2
Respiratory, thoracic and mediastinal disorders						
Cough [A] †	3/45 (6.67%)	4	2/48 (4.17%)	3	8/44 (18.18%)	11
Epistaxis [A] †	0/45 (0%)	0	0/48 (0%)	0	2/44 (4.55%)	3
Oropharyngeal pain [A] †	1/45 (2.22%)	2	1/48 (2.08%)	1	2/44 (4.55%)	2
Rales [A] †	0/45 (0%)	0	2/48 (4.17%)	2	2/44 (4.55%)	2
Skin and subcutaneous tissue disorders						
Alopecia [A] †	1/45 (2.22%)	1	3/48 (6.25%)	3	3/44 (6.82%)	3
Hyperhidrosis [A] †	1/45 (2.22%)	2	0/48 (0%)	0	2/44 (4.55%)	3
Pruritus [A] †	3/45 (6.67%)	4	1/48 (2.08%)	1	1/44 (2.27%)	1
Rash [A] †	3/45 (6.67%)	3	2/48 (4.17%)	2	3/44 (6.82%)	9
Vascular disorders						
Hot flush [A] †	19/45 (42.22%)	27	18/48 (37.5%)	18	17/44 (38.64%)	20
Hypertension [A] †	3/45 (6.67%)	3	3/48 (6.25%)	3	3/44 (6.82%)	4
Orthostatic hypertension [A] †	0/45 (0%)	0	0/48 (0%)	0	2/44 (4.55%)	2

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

The only disclosure restriction 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.

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