ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Grantor: CDER IND/IDE Number: 51,222 Serial Number:

Extension Study Investigating the Long-Term Safety of Degarelix Three-Month Depots in Patients With Prostate Cancer

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by:	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00268892

Purpose

The purpose of this extension study was to collect long-term safety and tolerability information to support a marketing authorisation application for a three-month dosage regimen of degarelix.

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 Different Three-Month Degarelix Dosing Regimens in Patients With Prostate Cancer

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [Time Frame: Baseline and up to 4.5 years] [Designated as safety issue: No]

  This outcome measure included incidence of markedly abnormal values in blood pressure (systolic and diastolic), pulse, and body weight during the trial. The table presents the number of participants with a normal baseline value and at least one post-baseline markedly abnormal value.

- Liver Function Tests [Time Frame: 4.5 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: 278
Study Start Date: January 2006
Primary Completion Date: September 2009
Study Completion Date: December 2009

Arms	Assigned Interventions
Experimental: Degarelix 240/240@40(1-3-6-9) Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (40 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (40 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).	Drug: Degarelix Participants who completed the main study initially continued with the same dose in the FE200486 CS15A extension study. A protocol amendment changed the dosage to 360 mg (60 mg/mL) or 480 mg (60 mg/mL). Drug supplied as a powder to be dissolved in the solvent for solution for injection. Degarelix given by subcutaneous injection every 3 months until the end of the study. Other Names: FE200486
Experimental: Degarelix 240/240@60(1-3-6-9) Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).	Drug: Degarelix Participants who completed the main study initially continued with the same dose in the FE200486 CS15A extension study. A protocol amendment changed the dosage to 360 mg (60 mg/mL) or 480 mg (60 mg/mL). Drug supplied as a powder to be dissolved in the solvent for solution for injection. Degarelix given by subcutaneous injection every 3 months until the end of the study. Other Names: FE200486
Experimental: Degarelix 240/240@60(1-4-7-10) Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 4,	Drug: Degarelix Participants who completed the main study initially continued with the same dose in the FE200486 CS15A extension study. A protocol amendment changed the dosage to 360 mg (60 mg/mL) or 480 mg (60 mg/mL).

Arms	Assigned Interventions
7, 10) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).	Drug supplied as a powder to be dissolved in the solvent for solution for injection. Degarelix given by subcutaneous injection every 3 months until the end of the study. Other Names: FE200486

Detailed Description:

The data include data from the participants who participated in both the main study FE200486 CS15 (NCT00113753) and the extension study FE200486 CS15A.

Eligibility

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

Criteria

Inclusion Criteria:

- Has given written consent prior to any study-related activity is performed. A study-related activity is defined as any procedure that would not have been performed during the normal management of the patient.
- Has successfully completed the main study.

Exclusion Criterion:

- Has been withdrawn from the main study.

Contacts and Locations

Locations

Belgium

UZ Gasthuisberg Leuven

Leuven, Belgium

Finland

Helsinki University Hospital, Maria Hospital, Building 11

Helsinki, Finland

Central Hospital, North Karelian

Joensuu, Finland

Oulu University Hospital

Oulu, Finland

Tampere University Hospital

Tampere, Finland

France

Centre Hospitalier Départemental des Oudairies, Chirurgie Urologie

La-Roche-sur-Yon, France

Fédération d'Urologie et Néphrologie, BP69 Hôpital Pasteur

Nice, France

Germany

Gemeinschaftspraxis Dres Effert und Benedic

Aachen, Germany

Montenegro

Clinical Center Novi Sad, Clinic of Urology

Novi Sad, Montenegro

Netherlands

Academic Medical Center, Urology

Amsterdam, Netherlands

St. Elisabeth Hospital

Tilburg, Netherlands

Romania

"Centrul Medical Privat" Prof. Dr. Ioiart Ioan"

Arad, Romania

Clinical Hospital "Prof. Dr. Theodor Burghele", Urology Department

Bucharest, Romania

University CF Hospital No. 2

Bucharest, Romania

Russian Federation

Andros Clinic

St. Petersburg, Russian Federation

City Hospital #26

St. Petersburg, Russian Federation

City Hospital #15

St. Petersburg, Russian Federation

Pavlov State Medical University, Outpatient Diagnostic Center affiliated with the Urology Department

St. Petersburg, Russian Federation

Pavlov State Medical University, Urology Department

St. Petersburg, Russian Federation

Serbia

Clinical Center of Serbia, Institute of Urology and Nephrology

Belgrade, Serbia

United Kingdom

Ward 13, NHS Forth Valley Acute Operating Division, Falkirk and District Royal Infirmary, Majors Loans

Falkirk, United Kingdom

Level 7, Urology Research Unit, Derriford Hospital

Plymouth, United Kingdom

Mount Vernon Cancer Centre, Marie Cuire Research Wing

Northwood, Middlesex, United Kingdom

Castle Hill Hospital
Hull, North Humberside, United Kingdom

Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals (Clinical Development Support)
Study ID Numbers:	FE200486 CS15A
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Russia: Ethics Committee Russia: FSI Scientific Center of Expertise of Medical Application Russia: Ministry of Health of the Russian Federation Russia: Pharmacological Committee, Ministry of Health Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Netherlands: Medical Ethics Review Committee (METC) Netherlands: Independent Ethics Committee Belgium: Federal Agency for Medicines and Health Products, FAMHP Belgium: Institutional Review Board France: Ministry of Health France: National Consultative Ethics Committee for Health and Life Sciences Romania: Ministry of Public Health Romania: National Authority for Scientific Research Romania: National Medicines Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency United Kingdom: Research Ethics Committee Germany: Ministry of Health Germany: Ethics Commission Finland: Ethics Committee Finland: Finnish Medicines Agency Serbia and Montenegro: Agency for Drugs and Medicinal Devices Serbia: Ethics Committee

Participant Flow

Recruitment Details	Participants who completed the main FE200486 CS15(NCT00113753) study (except those in US and Canada) were asked to continue into the FE200486 CS15A extension study.
Pre-Assignment Details	447 participants started and 374 participants completed the main CS15 study. Of these, 278 participants were recruited into the extension study CS15A and 203 participants signed the informed consent for dose shift.

Reporting Groups

	Description
Degarelix 240/240@40(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (40 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (40 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-4-7-10)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 4, 7, 10) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).

Overall Study

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)
Started	90	95	93
Switched to Higher Dose	59	68	76
Completed	51	53	54
Not Completed	39	42	39
Adverse Event	14	17	20
Lack of Efficacy	1	3	0
Withdrawal by Subject	14	15	13
Physician Decision	0	1	0
Lost to Follow-up	5	2	4

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)
Protocol Violation	0	1	0
Disease Progression	1	1	0
Trial Site Closed	4	2	2

Baseline Characteristics

Reporting Groups

	Description
Degarelix 240/240@40(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (40 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (40 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-4-7-10)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 4, 7, 10) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).

Baseline Measures

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)	Total
Number of Participants	90	95	93	278
Age, Continuous [1] [units: years] Mean (Standard Deviation)	72.7 (6.55)	73.3 (7.00)	71.8 (7.05)	72.6 (6.88)
Gender, Male/Female [1] [units: participants]				
Female	0	0	0	0
Male	90	95	93	278
Race (NIH/OMB) [1] [units: participants]				

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)	Total
American Indian or Alaska Native	0	0	1	1
Asian	0	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	3	5	3	11
White	87	89	88	264
More than one race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Body Weight [1] [units: kilogram] Mean (Standard Deviation)	76.7 (13.0)	76.9 (12.2)	76.5 (12.8)	76.7 (12.6)
Body Mass Index [1] [units: kilogram per square meter] Mean (Standard Deviation)	25.4 (4.14)	25.8 (3.93)	25.8 (4.16)	25.7 (4.07)
Curative Intent [2] [units: participants]				
Yes	10	12	7	29
No	80	83	86	249
Gleason Score [3] [units: participants]				
2-4	13	6	13	32
5-6	33	30	34	97
7-10	44	58	46	148
Stage of Prostate Cancer [4] [units: participants]				
Localized	34	37	36	107
Locally Advanced	26	26	28	80
Metastatic	16	19	20	55
Not Classifiable	14	13	9	36

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)	Total
Time since Prostate Cancer Diagnosis [1] [units: days] Mean (Standard Deviation)	469 (1079)	347 (824)	255 (583)	356 (852)

[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. A Gleason Score was missing for one participant in the Degarelix 240/240@60(1-3-6-9) group.

[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.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight
Measure Description	This outcome measure included incidence of markedly abnormal values in blood pressure (systolic and diastolic), pulse, and body weight during the trial. The table presents the number of participants with a normal baseline value and at least one post-baseline markedly abnormal value.
Time Frame	Baseline and up to 4.5 years
Safety Issue?	No

Analysis Population Description

The data include data from participants participating in both the main study (FE200486 CS15) and the extension study FE200486 CS15A.

Reporting Groups

	Description
Degarelix 240/240@40(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (40 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (40 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).

	Description
Degarelix 240/240@60(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-4-7-10)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 4, 7, 10) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).

Measured Values

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)
Number of Participants Analyzed	90	95	93
Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [units: participants]			
Diastolic blood pressure <=50 and decrease >=15	5	6	4
Diastolic blood pressure >=105 and increase >=15	7	6	8
Systolic blood pressure <=90 and decrease >=20	1	1	2
Systolic blood pressure >=180 and increase >=20	8	11	10
Heart rate <=50 and decrease >=15	9	10	5
Heart rate >=120 and increase >=15	1	4	1
Body weight decrease of >=7 percent	7	8	4
Body weight increase of >=7 percent	32	35	41

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	4.5 years

Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/240@40(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (40 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (40 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-4-7-10)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 4, 7, 10) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).

Measured Values

	Degarelix 240/240@40(1-3-6-9)	Degarelix 240/240@60(1-3-6-9)	Degarelix 240/240@60(1-4-7-10)
Number of Participants Analyzed	90	95	93
Liver Function Tests [units: participants]			
Abnormal alanine aminotransferase (ALAT)	22	22	17
Abnormal aspartate aminotransferase	18	25	19
Abnormal bilirubin	4	5	3
ALAT >3x upper limit of normal (ULN)	3	2	3
ALAT >3x ULN, bilirubin >1.5x ULN	0	0	0

Reported Adverse Events

Time Frame	4.5 years.
Additional Description	Each participant'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 participant's Case Report Form.

Reporting Groups

	Description
Degarelix 240/240@40(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (40 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (40 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-3-6-9)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 3, 6, and 9) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).
Degarelix 240/240@60(1-4-7-10)	Participants in this arm who completed the main study continued with the same dose (240 mg (40 mg/mL) starting dose and 240 mg (60 mg/mL) at months 1, 4, 7, 10) in the extension study (240 mg (60 mg/mL) every three months). A protocol amendment in June 2006 changed the dosage to 360 mg or 480 mg (60 mg/mL).

Serious Adverse Events

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	30/90 (33.33%)		24/95 (25.26%)		21/93 (22.58%)	
Cardiac disorders						
Acute myocardial infarction [A] †	2/90 (2.22%)	2	0/95 (0%)	0	0/93 (0%)	0
Angina Pectoris [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Artrial Flutter [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Atrial fibrillation [A] †	1/90 (1.11%)	1	1/95 (1.05%)	1	0/93 (0%)	0
Atrioventricular block complete [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Cardiac Failure [A] †	1/90 (1.11%)	1	0/95 (0%)	0	1/93 (1.08%)	1
Cardiac arrest [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Cardio-respiratory arrest [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Coronary artery disease [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Coronary artery stenosis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Myocardial ischaemia [A] †	1/90 (1.11%)	1	1/95 (1.05%)	1	1/93 (1.08%)	1
Right ventricular failure [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Sick sinus syndrome [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Endocrine disorders						
Hypoparathyroidism [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Eye disorders						
Eye haemorrhage [A] †	0/90 (0%)	0	1/95 (1.05%)	2	0/93 (0%)	0
Gastrointestinal disorders						
Abdominal pain [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Abdominal pain lower [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Constipation [A] †	0/90 (0%)	0	1/95 (1.05%)	1	1/93 (1.08%)	1
Crohn's disease [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Gastritis [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Gastrointestinal haemorrhage [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Gastrointestinal hypomotility [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Gastrointestinal necrosis [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Haematemesis [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Haemorrhoids [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Ileus [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Inguinal hernia [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Intestinal infarction [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Pancreatic cyst [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Volvulus [A] †	0/90 (0%)	0	1/95 (1.05%)	1	1/93 (1.08%)	1
Vomiting [A] †	1/90 (1.11%)	1	1/95 (1.05%)	1	0/93 (0%)	0
General disorders						
Adverse drug reaction [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Disease progression [A] †	1/90 (1.11%)	1	0/95 (0%)	0	1/93 (1.08%)	1
Fatigue [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Pyrexia [A] †	1/90 (1.11%)	1	1/95 (1.05%)	1	0/93 (0%)	0
Sudden death [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Hepatobiliary disorders						
Cholecystitis acute [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Infections and infestations						
Appendicitis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Cellulitis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Erysipelas [A] †	0/90 (0%)	0	1/95 (1.05%)	1	1/93 (1.08%)	1
Gastroenteritis [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Mycotoxicosis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Pneumonia [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Pyelonephritis [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Pyelonephritis acute [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Respiratory tract infection [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Staphylococcal sepsis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Urinary tract infection [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Injury, poisoning and procedural complications						
Ankle fracture [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Brain contusion [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Femur fracture [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Hand fracture [A] †	1/90 (1.11%)	1	1/95 (1.05%)	1	0/93 (0%)	0
Hip fracture [A] †	3/90 (3.33%)	3	1/95 (1.05%)	1	0/93 (0%)	0
Joint dislocation [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Post procedural haematuria [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Radius fracture [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Rib fracture [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Subdural haematoma [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Ulna fracture [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Investigations						
Blood pressure increased [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Investigation [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Prostatic specific antigen increased [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Metabolism and nutrition disorders						

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Dehydration [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	2
Osteoarthiritis [A] †	1/90 (1.11%)	1	1/95 (1.05%)	1	0/93 (0%)	0
Osteoporotic fracture [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Pathological fracture [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Rhabdomyolysis [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Bladder transitional cell [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Carcinoma [A] †	0/90 (0%)	0	0/95 (0%)	0	0/93 (0%)	0
Lung neoplasm [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Lymphoma [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Metastates to spine [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Metastatic pain [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Prostate cancer [A] †	1/90 (1.11%)	1	0/95 (0%)	0	2/93 (2.15%)	2
Prostate cancer metastatic [A] †	2/90 (2.22%)	2	1/95 (1.05%)	1	1/93 (1.08%)	1
Rectal cancer [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Throat cancer [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Nervous system disorders						
Cerebal infarction [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Cerebrovascular accident [A] †	0/90 (0%)	0	1/95 (1.05%)	1	1/93 (1.08%)	1
Cerebrovascular disorder [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Dementia Alzheimer's type [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Dizziness [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Haemorrhagic stroke [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Hemiparesis [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Ischaemic stroke [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Paraplegia [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Presyncope [A] †	0/90 (0%)	0	1/95 (1.05%)	2	0/93 (0%)	0
Transient ischaemic attack [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Psychiatric disorders						
Agitation [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Confusional state [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Renal and urinary disorders						
Bladder tamponade [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	1
Calculus ureteric [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Haematuria [A] †	0/90 (0%)	0	2/95 (2.11%)	2	1/93 (1.08%)	1
Hydronephrosis [A] †	0/90 (0%)	0	2/95 (2.11%)	4	1/93 (1.08%)	1
Renal colic [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Renal failure acute [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Urethral stenosis [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Urinary bladder polyp [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Urinary incontinence [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Urinary retention [A] †	7/90 (7.78%)	7	3/95 (3.16%)	3	0/93 (0%)	0

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Respiratory, thoracic and mediastinal disorders						
Chronic obstructive pulmonary disease [A] †	0/90 (0%)	0	0/95 (0%)	0	2/93 (2.15%)	2
Cough [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Epistaxis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Pulmonary embolism [A] †	0/90 (0%)	0	1/95 (1.05%)	1	1/93 (1.08%)	1
Skin and subcutaneous tissue disorders						
Hyperhidrosis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Stasis dermatitis [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0
Vascular disorders						
Arterial disorder [A] †	0/90 (0%)	0	0/95 (0%)	0	1/93 (1.08%)	2
Arterial stenosis limb [A] †	0/90 (0%)	0	1/95 (1.05%)	1	0/93 (0%)	0
Hypotension [A] †	1/90 (1.11%)	1	0/95 (0%)	0	0/93 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.0)

Other Adverse Events

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

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	72/90 (80%)		75/95 (78.95%)		69/93 (74.19%)	
Blood and lymphatic system disorders						
Anaemia [A] †	5/90 (5.56%)	6	7/95 (7.37%)	7	5/93 (5.38%)	6
Cardiac disorders						
Atrial Fibrillation [A] †	7/90 (7.78%)	12	9/95 (9.47%)	14	6/93 (6.45%)	6

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Eye disorders						
Cataract [A] †	6/90 (6.67%)	8	1/95 (1.05%)	1	3/93 (3.23%)	3
Gastrointestinal disorders						
Abdominal Pain [A] †	7/90 (7.78%)	10	6/95 (6.32%)	7	4/93 (4.3%)	4
Constipation [A] †	4/90 (4.44%)	4	6/95 (6.32%)	6	3/93 (3.23%)	8
Diarrhoea [A] †	4/90 (4.44%)	4	4/95 (4.21%)	6	5/93 (5.38%)	8
Nausea [A] †	5/90 (5.56%)	6	10/95 (10.53%)	15	2/93 (2.15%)	2
Vomiting [A] †	3/90 (3.33%)	4	5/95 (5.26%)	8	1/93 (1.08%)	5
General disorders						
Aspartate Aminotransferase Increase [A] †	4/90 (4.44%)	4	3/95 (3.16%)	4	5/93 (5.38%)	5
Fatigue [A] †	10/90 (11.11%)	13	9/95 (9.47%)	14	8/93 (8.6%)	8
Influenza [A] †	4/90 (4.44%)	4	5/95 (5.26%)	5	7/93 (7.53%)	9
Injection Site Erythema [A] †	15/90 (16.67%)	29	14/95 (14.74%)	32	6/93 (6.45%)	8
Injection Site Induration [A] †	7/90 (7.78%)	7	4/95 (4.21%)	5	4/93 (4.3%)	8
Injection Site Mass [A] †	5/90 (5.56%)	10	2/95 (2.11%)	2	1/93 (1.08%)	1
Injection Site Nodule [A] †	6/90 (6.67%)	8	3/95 (3.16%)	7	4/93 (4.3%)	6
Injection Site Pain [A] †	24/90 (26.67%)	55	24/95 (25.26%)	64	16/93 (17.2%)	36
Injection Site Pruritus [A] †	5/90 (5.56%)	6	2/95 (2.11%)	3	1/93 (1.08%)	7
Injection Site Swelling [A] †	5/90 (5.56%)	12	10/95 (10.53%)	26	3/93 (3.23%)	3
Nasopharyngitis [A] †	5/90 (5.56%)	10	9/95 (9.47%)	16	3/93 (3.23%)	5

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Oedema Peripheral [A] †	4/90 (4.44%)	4	6/95 (6.32%)	6	4/93 (4.3%)	4
Pyrexia [A] †	12/90 (13.33%)	31	9/95 (9.47%)	20	7/93 (7.53%)	22
Urinary Tract Infection [A] †	6/90 (6.67%)	8	9/95 (9.47%)	17	6/93 (6.45%)	6
Investigations						
Alanine Aminotransferase Increased [A] †	6/90 (6.67%)	6	5/95 (5.26%)	6	5/93 (5.38%)	5
Weight Decreased [A] †	4/90 (4.44%)	4	7/95 (7.37%)	7	4/93 (4.3%)	4
Weight Increased [A] †	11/90 (12.22%)	12	9/95 (9.47%)	10	7/93 (7.53%)	7
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	10/90 (11.11%)	13	7/95 (7.37%)	10	6/93 (6.45%)	14
Back Pain [A] †	9/90 (10%)	10	5/95 (5.26%)	7	6/93 (6.45%)	12
Musculoskeletal Pain [A] †	5/90 (5.56%)	5	1/95 (1.05%)	2	3/93 (3.23%)	6
Nervous system disorders						
Dizziness [A] †	7/90 (7.78%)	9	9/95 (9.47%)	12	4/93 (4.3%)	6
Headache [A] †	5/90 (5.56%)	7	4/95 (4.21%)	4	3/93 (3.23%)	20
Psychiatric disorders						
Insomnia [A] †	2/90 (2.22%)	3	7/95 (7.37%)	7	1/93 (1.08%)	1
Renal and urinary disorders						
Urinary retention [A] †	2/90 (2.22%)	2	5/95 (5.26%)	6	2/93 (2.15%)	2
Skin and subcutaneous tissue disorders						
Hyperhidrosis [A] †	2/90 (2.22%)	3	5/95 (5.26%)	5	3/93 (3.23%)	4
Rash [A] †	1/90 (1.11%)	3	5/95 (5.26%)	9	0/93 (0%)	0

	Degarelix 240/240@40(1-3-6-9)		Degarelix 240/240@60(1-3-6-9)		Degarelix 240/240@60(1-4-7-10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Vascular disorders						
Hot Flush [A] †	31/90 (34.44%)	33	27/95 (28.42%)	29	32/93 (34.41%)	38
Hypertension [A] †	4/90 (4.44%)	5	6/95 (6.32%)	6	5/93 (5.38%)	5

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.0)

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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