ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Grantor: CDER IND/IDE Number: 51,222 Serial Number: 066

A Comparative Study of Degarelix Three-month Depot in Three Different Dosing Regimens in Patients With Prostate Cancer

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by:	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00116753

Purpose

The rationale of the study was to evaluate different degarelix dosing regimens for a three-month interval that was to produce and maintain castration in prostate cancer patients through immediate and prolonged testosterone suppression, and to provide confirmatory evidence of the safety of degarelix.

Condition	Intervention	Phase
Prostate Cancer	Drug: Degarelix	Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: An Open-label Multi-center, Randomized Parallel Group Comparison of Efficacy and Safety of Degarelix Three-Month Depot in Three Different Dosing Regimens in Patients With Prostate Cancer

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study [Time Frame: From Day 28 to 12 or 13 months] [Designated as safety issue: No]

  Figure in the table give the number of participants with all testosterone values <=0.5 ng/mL from Day 28 to the end of the study.

Secondary Outcome Measures:

- Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study [Time Frame: From after Day 28 to 12 or 13 months] [Designated as safety issue: No]
  Figures in the table give the number of participants with all testosterone values <=0.5 ng/mL after the dose at Day 28 to end of study. Thus, the testosterone response after the initial dose is not included in this outcome measure.
- Number of Participants With Testosterone <=0.5 ng/mL at Day 28 [Time Frame: 28 Days] [Designated as safety issue: No]
  Figures in the table give number of participants with testosterone <=0.5 ng/mL 28 days after the initial dose of trial medication.
- Liver Function Tests [Time Frame: 12 or 13 months] [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.
- Number of Participants With Markedly Abnormal Change in Vital Signs and Body Weight as Compared to Baseline [Time Frame: 12 or 13 months] [Designated as safety issue: No]
  This outcome measure included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight. The table presents the number of participants with normal baseline and at least one post-baseline markedly abnormal value.

Enrollment: 460
Study Start Date: January 2005
Primary Completion Date: November 2006
Study Completion Date: November 2006

Arms	Assigned Interventions
Active Comparator: Degarelix 240@40/240@40 (1,3,6,9) 240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.	Drug: Degarelix Drug: Degarelix subcutaneous 240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9 Other Names: FE200486
Active Comparator: Degarelix 240@40/240@60(1,3,6,9) 240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.	Drug: Degarelix Drug: Degarelix subcutaneous 240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9 Other Names: FE200486
Active Comparator: Degarelix 240@40/240@60(1,4,7,10) 240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.	Drug: Degarelix Drug: Degarelix subcutaneous 240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10 Other Names: FE200486

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 before 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 a histologically confirmed (Gleason graded) adenocarcinoma of the prostate (all stages) in whom endocrine treatment, except for neoadjuvant hormonal therapy, is indicated. This includes patients with rising PSA after having undergone prostatectomy or radiotherapy with curative intention.
- Is a male patient aged 18 years or over.
- Has a baseline serum testosterone level above the lower limit of normal range, globally defined as >2.2 ng/mL.
- Has an ECOG (Eastern Cooperative Oncology Group) score of 2.
- Has a PSA value of 2 ng/mL.
- Has a life expectancy of at least 13 months.

Exclusion Criteria:

- Has had previous or is currently under hormonal management of prostate cancer (surgical castration or other hormonal manipulation, e.g. GnRH agonists, GnRH antagonists, antiandrogens, oestrogens). However, patients having undergone prostatectomy or radiotherapy with curative intention, neoadjuvant hormonal therapy is accepted for a maximal duration of 6 months. This treatment should have been terminated at least 6 months prior to the Screening Visit.
- Is considered to be a candidate for curative therapy, i.e. radical prostatectomy or radiotherapy within 13 months from Screening Visit.
- Has a history of, or predisposition to, severe hypersensitivity reactions such as severe asthma (defined as a need for daily treatment with inhalation steroids to control the asthma), anaphylactic reactions, or chronic or recurrent urticaria and/or angioedema.
- Has hypersensitivity towards any component of the investigational medicinal product. 5. Has had a cancer disease within the last five years except for prostate cancer and surgically removed basal or squamous cell carcinoma of the skin.
- Has a known or suspected hepatic or symptomatic biliary disease.
- Has elevated serum ALT level above upper level of normal range or serum total bilirubin level above upper level of normal range as measured by the laboratory at the Screening Visit.
- Has other clinically significant laboratory abnormalities, which in the judgment of the investigator would interfere with the patient's participation in this study or evaluation of study results.
- Has a clinically significant disorder (other than prostate cancer) or any other condition, including excessive alcohol or drug abuse, which may interfere with study participation or which may affect the conclusion of the study as judged by the investigator.
- Has a mental incapacity or language barriers precluding adequate understanding or cooperation.
- Has received an investigational drug within the last 28 days preceding Screening Visit or longer if considered by the investigator to possibly influence the outcome of the current study.
- Has previously participated in any degarelix study.

Contacts and Locations

Locations

United States, Alabama
Urology Centers of Alabama
Homewood, Alabama, United States, 35209
Medical Affiliationed Research Center
Huntsville, Alabama, United States, 35801
United States, Alaska
Alaska Clinical Research Center, LLC
Anchorage, Alaska, United States, 99508
United States, California
Advanced Urology Medical Center
Anaheim, California, United States, 92801
Center for Urological Research
La Mesa, California, United States, 91942
South Orange County Medical Research Center
Laguna Woods,, California, United States, 92653
West Coast Clinical Research
Tarzana, California, United States, 91356
Western Clinical Research
Torrance, California, United States, 90505
United States, Colorado
Urology Research Option
Aurora, Colorado, United States, 80012
United States, Florida
South Florida Medical Research
Aventura, Florida, United States, 33180
SW Florida Urological Associates
Fort Myers, Florida, United States, 33907
RT Services, Inc
Ft Myers, Florida, United States, 33901
United States, Louisiana
Regional Urology
Shreveport, Louisiana, United States, 71106
United States, Mississippi
Mississippi Urology Clinic
Jackson, Mississippi, United States, 39202
United States, Missouri
University of Missouri, Urology, Deptof Surgery
Columbia, Missouri, United States, 65212
Kansas City Urology Care
Kansas City, Missouri, United States, 64131
United States, North Carolina
Northeast Urology Research
Concord, North Carolina, United States, 28025
The Urology Center
Greensboro, North Carolina, United States, 27401

United States, Pennsylvania
State College Urologic Association
State College, Pennsylvania, United States, 16801
United States, South Carolina
Grand Strand Urology
Myrtle Beach, South Carolina, United States, 29572
United States, Texas
Urology Association of Northern Texas
Fort Worth, Texas, United States, 76104
Urology San Antonio Research
San Antonio, Texas, United States, 78229
United States, Washington
Seatle Urology Research Centre
Seattle, Washington, United States, 98166
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Leuven, Belgium
Canada, British Columbia
Southern Interior Medical Research Corp
Kelowna, British Columbia, Canada
Andreou Researce
Surrey, British Columbia, Canada
Can-Med Clinical Research Inc.
Victoria, British Columbia, Canada
Canada, Ontario
The Male/Female Health Centres and Research
Barrie, Ontario, Canada
Brantford Urology Research
Brantford, Ontario, Canada
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The Male Health Center
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Helsinki, Finland
Central Hospital, North Karelian, Dept. of Urology
Joensuu, Finland
Oulu University Hospital, Department of Surgery Division of Urology
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La Roche-sur-Yon, France
Fédération d'Urologie et Néphrologie
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Germany
Gemeinschaftspraxis Dres Effert und Benedic
Aachen, Germany
Klinik fuer Urologie, Vivantes Klinikum Am Urban
Berlin, Germany
Netherlands
Academic Medical Center, Urology
Amsterdam, Netherlands
St. Elisabeth Hospital
Tilburg, Netherlands
Romania
Centrul Medical Privat
Arad, Romania
Clinical Hospital "Prof. Dr. Theodor Burghele", Urology Department
Bucharest, Romania
University CF Hospital No.2, Urology Clinic
Bucharest, Romania
Russian Federation
Andros Clinic
Saint Petersburg, Russian Federation
City Hospital #26
Saint Petersburg, Russian Federation
City Hospital #15
Saint Petersburg, Russian Federation
Pavlov State Medical University, Urology Department
Saint Petersburg, Russian Federation
Pavlov State Medical University, Outpatient Diagnostic Center affiliated with the Urology Department
Saint Petersburg, Russian Federation
United Kingdom
Ward 10, NHS Forth Valley Acute Operating Division, Falkirk and District Royal Infirmary
Falkirk, United Kingdom
Mount Vernon Cancer Centre, Marie Curie Research Wing
Middlesex, United Kingdom
Castle Hill Hospital, Dept. Urology
North Humberside, United Kingdom
Level 7, Urology Research Unit, Derriford Hospital

Plymouth, United Kingdom

Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals (Clinical Development Support)
Study ID Numbers:	FE200486 CS15
Health Authority:	United States: Food and Drug Administration Canada: Health Canada

Study Results

Participant Flow

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Overall Study

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Started	153 [1]	155	152
ITT Population	150	150	147
Completed	121	125	128
Not Completed	32	30	24
Adverse Event	16	10	7
Withdrawal by Subject	11	12	8
Lost to Follow-up	0	2	1
Protocol Violation	0	0	1

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Did not Fulfil Eligibility Criteria	1	1	3
Disease Progression	3	4	3
Abnormal Echocardiogram	0	0	1
Progressive Parkinson's Disease	1	0	0
Dosing Error	0	1	0

[1] Randomised.

Baseline Characteristics

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Baseline Measures

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)	Total
Number of Participants	150	150	147	447
Age, Categorical [1] [units: participants]				
<=18 years	0	0	0	0
Between 18 and 65 years	21	19	20	60
>=65 years	129	131	127	387
Age, Continuous [2] [units: years] Median (Full Range)	75 (50 to 86)	75 (49 to 88)	75 (50 to 90)	75 (49 to 90)
Gender, Male/Female [2] [units: participants]				

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)	Total
Female	0	0	0	0
Male	150	150	147	447
Race (NIH/OMB) [2] [units: participants]				
American Indian or Alaska Native	0	1	1	2
Asian	0	3	1	4
Native Hawaiian or Other Pacific Islander	0	0	1	1
Black or African American	9	15	8	32
White	141	131	136	408
More than one race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Curative Intent [3] [units: Participants]				
Yes	17	22	17	56
No	133	128	130	391
Gleason Score [4] [units: participants]				
2-4	16	9	15	40
5-6	52	43	61	156
7-10	82	97	70	249
Stage of Prostate Cancer [5] [units: participants]				
Localized	56	62	66	184
Locally advanced	40	31	34	105
Metastatic	28	30	26	84
Not classifiable	26	27	21	74

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)	Total
Time Since Prostate Cancer Diagnosis [2] [units: days] Mean (Standard Deviation)	465 (1041)	388 (968)	346 (738)	400 (925)
Body Weight [2] [units: kilogram] Mean (Standard Deviation)	78.5 (14.6)	78.4 (13.9)	77.4 (12.9)	78.1 (13.8)
Body Mass Index [2] [units: kilogram per square meter] Mean (Standard Deviation)	25.9 (4.25)	26.3 (4.42)	26.0 (4.24)	26.0 (4.30)
Serum Testosterone Levels [2] [units: nanogram per milliliter] Median (Inter-Quartile Range)	4.43 (3.19 to 5.74)	4.00 (3.21 to 5.06)	4.07 (2.85 to 5.39)	4.23 (3.08 to 5.45)
Serum Prostate Specific Antigen Levels [2] [units: nanogram per milliliter] Median (Inter-Quartile Range)	13.8 (6.90 to 48.9)	16.6 (9.00 to 40.5)	15.6 (6.20 to 36.2)	15.6 (7.30 to 40.5)

[1] ITT population. ITT refers to the intent-to-treat population, which includes participants who were both randomized and treated.

[2] ITT population.

[3] ITT population. Curative intent refers to radical prostatectomy or radiotherapy.

[4] ITT population. 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. The Gleason scores were missing for two participants.

[5] ITT population. Stage of prostate cancer was classified according to the Tumour, Nodule and Metastatic classification that is a cancer staging system that describes the extent of cancer. T describes the size of the tumor and whether it has invaded nearby tissue, N describes regional lymph nodes that are involved, and M describes distant metastasis.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study
Measure Description	Figure in the table give the number of participants with all testosterone values <=0.5 ng/mL from Day 28 to the end of the study.

Time Frame	From Day 28 to 12 or 13 months
Safety Issue?	No

Analysis Population Description

Observed Cases in ITT population.

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Measured Values

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Number of Participants Analyzed	120	127	129
Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study [units: participants]	94	101	110

Statistical Analysis 1 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of partcipants]
	Estimated Value	78.3
	Confidence Interval	(2-Sided) 96.5% 69 to 86

	Estimation Comments	Estimated value is the percentage of participants with all testosterone values from Day 28 to end of study <=0.5 ng/mL. Measure dispersion is the 96.5% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 2 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	79.5
	Confidence Interval	(2-Sided) 96.5% 71 to 87
	Estimation Comments	Estimated value is the percentage of participants with all testosterone values from Day 28 to end of study <=0.5 ng/mL. Measure dispersion is the 96.5% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 3 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	85.3
	Confidence Interval	(2-Sided) 96.5% 77 to 91
	Estimation Comments	Estimated value is the percentage of participants with all testosterone values from Day 28 to end of study <=0.5 ng/mL. Measure dispersion is the 96.5% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 4 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9), Degarelix 240@40/240@60 (1,3,6,9), Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3022
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

Statistical Analysis 5 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9), Degarelix 240@40/240@60 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7797
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

Statistical Analysis 6 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9), Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1557
	Comments	[Not specified]

	Method	Mantel Haenszel
	Comments	[Not specified]

Statistical Analysis 7 for Number of Participants With Testosterone Level <=0.5 ng/mL From Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,3,6,9), Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2208
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study
Measure Description	Figures in the table give the number of participants with all testosterone values <=0.5 ng/mL after the dose at Day 28 to end of study. Thus, the testosterone response after the initial dose is not included in this outcome measure.
Time Frame	From after Day 28 to 12 or 13 months
Safety Issue?	No

Analysis Population Description

Observed Cases in ITT population.

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Measured Values

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Number of Participants Analyzed	119	126	129
Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study [units: participants]	96	101	111

Statistical Analysis 1 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	80.7
	Confidence Interval	(2-Sided) 96.5% 72 to 88
	Estimation Comments	Estimated value is the percentage of participants with all testosterone values from after Day 28 to end of study <=0.5 ng/mL. Measure dispersion is the 96.5% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 2 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	80.2
	Confidence Interval	(2-Sided) 96.5%

		72 to 87
	Estimation Comments	Estimated value is the percentage of participants with all testosterone values from Day 28 to end of study <=0.5 ng/mL. Measure dispersion is the 96.5% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 3 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	86.0
	Confidence Interval	(2-Sided) 96.5% 78 to 92
	Estimation Comments	Estimated value is the percentage of participants with all testosterone values from Day 28 to end of study <=0.5 ng/mL. Measure dispersion is the 96.5% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 4 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9), Degarelix 240@40/240@60 (1,3,6,9), Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3830
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

Statistical Analysis 5 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9), Degarelix 240@40/240@60 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9587
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

Statistical Analysis 6 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9), Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2579
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

Statistical Analysis 7 for Number of Participants With Testosterone Level <=0.5 ng/mL After the Dose at Day 28 Until the End of the Study

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,3,6,9), Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2072
	Comments	[Not specified]

	Method	Mantel Haenszel
	Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Number of Participants With Testosterone <=0.5 ng/mL at Day 28
Measure Description	Figures in the table give number of participants with testosterone <=0.5 ng/mL 28 days after the initial dose of trial medication.
Time Frame	28 Days
Safety Issue?	No

Analysis Population Description

Observed Cases in ITT population.

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Measured Values

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Number of Participants Analyzed	146	146	145
Number of Participants With Testosterone <=0.5 ng/mL at Day 28 [units: participants]	142	143	142

Statistical Analysis 1 for Number of Participants With Testosterone <=0.5 ng/mL at Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@40 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	97.3
	Confidence Interval	(2-Sided) 95% 93 to 99
	Estimation Comments	Estimated value is the percentage of participants with testosterone <=0.5 ng/mL at Day 28. Measure dispersion is the 95% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 2 for Number of Participants With Testosterone <=0.5 ng/mL at Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,3,6,9)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	97.9
	Confidence Interval	(2-Sided) 95% 94 to 100
	Estimation Comments	Estimated value is the percentage of participants with testosterone <=0.5 ng/mL at Day 28. Measure dispersion is the 95% two-sided confidence interval which was calculated by the Clopper-Pearson method.

Statistical Analysis 3 for Number of Participants With Testosterone <=0.5 ng/mL at Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240@40/240@60 (1,4,7,10)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage of participants]
	Estimated Value	97.9
	Confidence Interval	(2-Sided) 95%

		94 to 100
	Estimation Comments	Estimated value is the percentage of participants with testosterone <=0.5 ng/mL at Day 28. Measure dispersion is the 95% two-sided confidence interval which was calculated by the Clopper-Pearson method.

4. Secondary 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	12 or 13 months
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Measured Values

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Number of Participants Analyzed	150	150	147
Liver Function Tests [units: participants]			
Abnormal alanine aminotransferase (ALAT)	60	56	57
Abnormal aspartate aminitransferase	40	45	50
Abnormal bilirubin	4	7	2
ALAT >3x upper limit of normal (ULN)	2	2	6

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
ALAT >3x ULN, bilirubin 1.5x ULN	0	0	0

5. Secondary Outcome Measure:

Measure Title	Number of Participants With Markedly Abnormal Change in Vital Signs and Body Weight as Compared to Baseline
Measure Description	This outcome measure included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight. The table presents the number of participants with normal baseline and at least one post-baseline markedly abnormal value.
Time Frame	12 or 13 months
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
Degarelix 240@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Measured Values

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Number of Participants Analyzed	150	150	147
Number of Participants With Markedly Abnormal Change in Vital Signs and Body Weight as Compared to Baseline [units: participants]			
Diastolic blood pressure <=50 and decrease >=15	4	6	2
Diastolic blood pressure >=105 and increase >=15	5	7	7
Systolic blood pressure <=90 and decrease >=20	1	3	3

	Degarelix 240@40/240@40 (1,3,6,9)	Degarelix 240@40/240@60 (1,3,6,9)	Degarelix 240@40/240@60 (1,4,7,10)
Systolic blood pressure >=180 and increase >=20	5	10	12
Heart rate <=50 and decrease >=15	6	7	8
Heart rate >=120 and increase >=15	1	2	0
Body weight decrease of >=7 percent	5	4	0
Body weight increase of >=7 percent	21	19	17

Reported Adverse Events

Time Frame	12 or 13 months.
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@40/240@40 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (40 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,3,6,9)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 3, 6 and 9.
Degarelix 240@40/240@60 (1,4,7,10)	240 mg (40 mg/mL) initiation dose, maintenance dose 240 mg (60 mg/mL) at months 1, 4, 7 and 10.

Serious Adverse Events

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	28/150 (18.67%)		25/150 (16.67%)		19/147 (12.93%)	
Blood and lymphatic system disorders						
Anaemia [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Cardiac disorders						
Acute coronary syndrome [A] †	0/150 (0%)	0	1/150 (0.67%)	2	0/147 (0%)	0
Acute myocardial infarction [A] †	2/150 (1.33%)	3	0/150 (0%)	0	0/147 (0%)	0
Atrial fibrillation [A] †	1/150 (0.67%)	1	1/150 (0.67%)	1	0/147 (0%)	0
Atrioventricular block complete [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Cardiac failure [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Cardiac failure congestive [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Cardio-respiratory arrest [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Coronary artery disease [A] †	0/150 (0%)	0	2/150 (1.33%)	2	1/147 (0.68%)	1
Coronary artery stenosis [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Myocardial infarction [A] †	2/150 (1.33%)	2	0/150 (0%)	0	0/147 (0%)	0
Myocardial ischaemia [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Ventricular fibrillation [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Endocrine disorders						
Hypoparathyroidism [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Eye disorders						
Eye haemorrhage [A] †	0/150 (0%)	0	1/150 (0.67%)	2	0/147 (0%)	0
Gastrointestinal disorders						
Abdominal pain [A] †	1/150 (0.67%)	1	0/150 (0%)	0	2/147 (1.36%)	2
Acute abdomen [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Constipation [A] †	0/150 (0%)	0	2/150 (1.33%)	2	1/147 (0.68%)	1
Crohn's disease [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Gastrointestinal hypomotility [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Haematemesis [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Ileus [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Inguinal hernia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Inguinal hernia, obstructive [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Intestinal infarction [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Oesophageal stenosis [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Pancreatic cyst [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Peptic ulcer [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
General disorders						
Asthenia [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Chest pain [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Fatigue [A] †	1/150 (0.67%)	1	1/150 (0.67%)	1	0/147 (0%)	0
Injection site haematoma [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Pyrexia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	1/147 (0.68%)	1
Hepatobiliary disorders						
Hepatic failure [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Jaundice [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Infections and infestations						
Bacteraemia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Gastroenteritis [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Infection [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Injection site infection [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Lobar pneumonia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Pneumonia [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Pneumonia legionella [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Respiratory tract infection [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Sepsis [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Injury, poisoning and procedural complications						
Fall [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Head injury [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Hip fracture [A] †	1/150 (0.67%)	1	0/150 (0%)	0	1/147 (0.68%)	1
Humerus fracture [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Procedural pain [A] †	0/150 (0%)	0	1/150 (0.67%)	2	0/147 (0%)	0
Investigations						
Blood pressure increased [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Prostatic specific antigen increased [A] †	2/150 (1.33%)	2	0/150 (0%)	0	0/147 (0%)	0
Metabolism and nutrition disorders						
Dehydration [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Hyponatraemia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Arthritis [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Lumbar spinal stenosis [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Osteoarthritis [A] †	1/150 (0.67%)	1	2/150 (1.33%)	2	1/147 (0.68%)	1
Spinal column stenosis [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Acute myeloid leukaemia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Hepatic cancer metastatic [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Lung neoplasm [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Lymphoma [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Metastases to bone [A] †	2/150 (1.33%)	2	1/150 (0.67%)	1	0/147 (0%)	0
Metastatic neoplasm [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Metastatic pain [A] †	1/150 (0.67%)	1	1/150 (0.67%)	1	0/147 (0%)	0
Parathyroid tumour benign [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Rectal neoplasm [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Nervous system disorders						
Carotid artery stenosis [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Cerebral infarction [A] †	1/150 (0.67%)	1	0/150 (0%)	0	1/147 (0.68%)	1
Cerebrovascular accident [A] †	0/150 (0%)	0	1/150 (0.67%)	1	1/147 (0.68%)	1
Dementia [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Epilepsy [A] †	1/150 (0.67%)	1	1/150 (0.67%)	1	0/147 (0%)	0
Haemorrhagic stroke [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Hemiparesis [A] †	1/150 (0.67%)	1	0/150 (0%)	0	1/147 (0.68%)	1

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Hemiplegia [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Ischaemic stroke [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Presyncope [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Spinal cord compression [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Syncope [A] †	1/150 (0.67%)	1	0/150 (0%)	0	1/147 (0.68%)	1
Transient ischaemic attack [A] †	1/150 (0.67%)	1	0/150 (0%)	0	1/147 (0.68%)	1
Psychiatric disorders						
Confusional state [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Delirium [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Renal and urinary disorders						
Haematuria [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Hydronephrosis [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Renal failure acute [A] †	2/150 (1.33%)	2	1/150 (0.67%)	1	0/147 (0%)	0
Urethral stenosis [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Urinary incontinence [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Urinary retention [A] †	4/150 (2.67%)	4	2/150 (1.33%)	2	0/147 (0%)	0
Reproductive system and breast disorders						
Prostatic obstruction [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Respiratory, thoracic and mediastinal disorders						
Acute respiratory failure [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0
Chronic obstructive pulmonary disease [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Cough [A] †	0/150 (0%)	0	1/150 (0.67%)	1	0/147 (0%)	0

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Dyspnoea exertional [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Pulmonary embolism [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Respiratory failure [A] †	1/150 (0.67%)	1	1/150 (0.67%)	1	0/147 (0%)	0
Vascular disorders						
Aneurysm ruptured [A] †	1/150 (0.67%)	1	0/150 (0%)	0	0/147 (0%)	0
Arterial disorder [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	1
Deep vein thrombosis [A] †	2/150 (1.33%)	2	0/150 (0%)	0	0/147 (0%)	0
Hypertension [A] †	1/150 (0.67%)	1	1/150 (0.67%)	1	0/147 (0%)	0
Orthostatic hypotension [A] †	0/150 (0%)	0	0/150 (0%)	0	1/147 (0.68%)	2

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (9.0)

Other Adverse Events

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

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	117/150 (78%)		110/150 (73.33%)		107/147 (72.79%)	
Blood and lymphatic system disorders						
Anaemia [A] †	7/150 (4.67%)	8	3/150 (2%)	3	6/147 (4.08%)	6
Gastrointestinal disorders						
Constipation [A] †	8/150 (5.33%)	8	10/150 (6.67%)	10	5/147 (3.4%)	9
General disorders						

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Fatigue [A] †	14/150 (9.33%)	17	11/150 (7.33%)	12	11/147 (7.48%)	12
Injection site erythema [A] †	31/150 (20.67%)	50	15/150 (10%)	29	17/147 (11.56%)	25
Injection site induration [A] †	7/150 (4.67%)	8	4/150 (2.67%)	5	9/147 (6.12%)	14
Injection site nodule [A] †	10/150 (6.67%)	16	5/150 (3.33%)	11	11/147 (7.48%)	22
Injection site pain [A] †	45/150 (30%)	85	31/150 (20.67%)	68	31/147 (21.09%)	53
Injection site swelling [A] †	5/150 (3.33%)	10	13/150 (8.67%)	24	4/147 (2.72%)	6
Pyrexia [A] †	12/150 (8%)	18	3/150 (2%)	8	6/147 (4.08%)	7
Infections and infestations						
Nasopharyngitis [A] †	9/150 (6%)	12	11/150 (7.33%)	15	4/147 (2.72%)	4
Urinary tract infection [A] †	11/150 (7.33%)	17	9/150 (6%)	11	9/147 (6.12%)	11
Investigations						
Alanine aminotransferase increased [A] †	5/150 (3.33%)	5	6/150 (4%)	7	8/147 (5.44%)	9
Weight increased [A] †	11/150 (7.33%)	11	9/150 (6%)	10	3/147 (2.04%)	3
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	12/150 (8%)	13	6/150 (4%)	6	6/147 (4.08%)	9
Back pain [A] †	7/150 (4.67%)	8	8/150 (5.33%)	10	7/147 (4.76%)	10
Nervous system disorders						
Dizziness [A] †	10/150 (6.67%)	12	12/150 (8%)	14	4/147 (2.72%)	4

	Degarelix 240@40/240@40 (1,3,6,9)		Degarelix 240@40/240@60 (1,3,6,9)		Degarelix 240@40/240@60 (1,4,7,10)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Psychiatric disorders						
Insomnia [A] †	4/150 (2.67%)	5	11/150 (7.33%)	11	0/147 (0%)	0
Renal and urinary disorders						
Pollakiuria [A] †	7/150 (4.67%)	7	3/150 (2%)	3	2/147 (1.36%)	2
Vascular disorders						
Hot flush [A] †	57/150 (38%)	60	52/150 (34.67%)	59	52/147 (35.37%)	57
Hypertension [A] †	4/150 (2.67%)	5	7/150 (4.67%)	7	3/147 (2.04%)	3

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (9.0)

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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