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Investigating Efficacy and Safety of Two Degarelix Three-Month Dosing Regimens in Patients With Prostate Cancer Requiring Androgen Ablation Therapy

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by:	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00468286

Purpose

The study will have two treatment groups, evaluating two Degarelix doses. First dose is the initial dose followed by a maintenance dose given every three months. The initial dose given to suppress the testosterone level and the three month maintenance dose to maintain the suppressed testosterone level over one year of treatment.

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-Centre, Randomised Parallel-Group Dose-Finding Study, Investigating Efficacy and Safety of Two Degarelix Three-Month Dosing Regimens in Patients With Prostate Cancer Requiring Androgen Ablation Therapy

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Probability of Testosterone at Castration Level (≤0.5 ng/mL) From Day 28 Through Day 364 [Time Frame: 1 year] [Designated as safety issue: No]
  Kaplan-Maier estimates of the cumulative probabilities of testosterone <=0.5 ng/mL from Day 28 to Day 364.

Secondary Outcome Measures:

- Serum Levels of Testosterone Over Time [Time Frame: 1 year] [Designated as safety issue: No]
- Probability of Testosterone at Castration Level (≤0.5 ng/mL) From Day 56 Through Day 364 [Time Frame: 1 year] [Designated as safety issue: No]
  Kaplan-Maier estimates of the cumulative probabilities of testosterone <=0.5 ng/mL from Day 56 to Day 364.
- Probability of no PSA Failure [Time Frame: 1 year] [Designated as safety issue: No]
  Cumulative probability (%) and 95% confidence interval (CI) for completing the study without PSA failure. PSA failure was defined as two consecutive increases of 50%, and at least 5 ng/mL, compared to nadir (lowest level of PSA achieved).
- Serum Levels of PSA Over Time [Time Frame: 1 year] [Designated as safety issue: No]
- Serum Levels of Follicle Stimulating Hormone (FSH) Over Time [Time Frame: 1 year] [Designated as safety issue: No]
- Serum Levels of Luteinizing Hormone (LH) Over Time [Time Frame: 1 year] [Designated as safety issue: No]
- Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [Time Frame: Baseline up to 1 year] [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: 1 year] [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: 133
Study Start Date: May 2007
Primary Completion Date: August 2008
Study Completion Date: August 2008

Arms	Assigned Interventions
Experimental: A Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.	Drug: Degarelix Experimental Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months. Drug: Degarelix Experimental Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Experimental: B Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by	Drug: Degarelix Experimental Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC

Arms	Assigned Interventions
injection under the skin) given after 1, 4, 7, & 10 months.	(by injection under the skin) given after 1, 4, 7, & 10 months.

Detailed Description:

An Open-Label, Multi-Centre, Randomized Parallel-Group Dose-Finding Study, Investigating Efficacy and Safety of Two Degarelix Three-Month Dosing Regimens in Patients with Prostrate Cancer Requiring Androgen Ablation Therapy.

Eligibility

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

Criteria

Inclusion / Exclusion Criteria:

- Patients, aged 18 years or older, with histologically proven prostate cancer of all stages in whom endocrine treatment is indicated.
- Screening testosterone level above the lower limit of normal range, globally defined as >2.2 ng/mL.
- Eastern Cooperative Oncology Group (ECOG) score of ≤2.
- Screening prostate-specific antigen (PSA) level ≥ ng/mL.

Contacts and Locations

Locations
United States, Alabama
Urology Centers of Alabama
Homewood, Alabama, United States, 35209
United States, California
South Orange County Medical Research Center
Laguna Woods, California, United States, 92653
United States, Florida
South Florida Medical Research
Aventura, Florida, United States, 33180
Florida Foundation for Healthcare Research
Ocala, Florida, United States, 34474
United States, Louisiana
Regional Urology
Shreveport, Louisiana, United States, 71106
United States, New York
Investigational site
Carmel, New York, United States, 10512

United States, North Carolina
The Urology Center
Greensboro, North Carolina, United States, 27403
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, Virginia
Urology of Virginia Research
Norfolk, Virginia, United States, 23502
United States, Washington
Urology Research Center
Seattle, Washington, United States, 98166
Canada
The Female/Male Health Centres
Ontario, Canada
Canada, British Columbia
Investigational site
Surrey, British Columbia, Canada
Investigational site
Victoria, British Columbia, Canada
Canada, Nova Scotia
Investigational site
Kentville, Nova Scotia, Canada
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Bucharest, Romania
"Prof Dr Th Burghele" Clinical Hospital
Bucharest, Romania
E-Uro Medical Center S.R.L.
Cluj-Napoca, Romania
Provita Center
Constanta, Romania
Sibiu County Clinical Hospital
Sibiu, Romania

Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals (Clinical Development Support)
Study ID Numbers:	FE200486 CS18
Health Authority:	United States: Food and Drug Administration United States: Institutional Review Board Romania: Ministry of Public Health Romania: National Medicines Agency Hungary: National Institute of Pharmacy Czech Republic: Ethics Committee Canada: Ethics Review Committee Canada: Health Canada

Study Results

Participant Flow

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Overall Study

	Degarelix 240/360 mg	Degarelix 240/480 mg
Started	67 [1]	66
Completed	60	54
Not Completed	7	12
Adverse Event	1	6
Protocol Violation	2	2
Withdrawal by Subject	4	3
Physician Decision	0	1

[1] Started=Intention to treat (ITT) population.

Baseline Characteristics

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Baseline Measures

	Degarelix 240/360 mg	Degarelix 240/480 mg	Total
Number of Participants	67	66	133
Age, Continuous [1] [units: years] Mean (Standard Deviation)	74.1 (7.3)	72.7 (8.5)	73.4 (7.9)
Gender, Male/Female [1] [units: participants]			
Female	0	0	0
Male	67	66	133
Race (NIH/OMB) [1] [units: participants]			

	Degarelix 240/360 mg	Degarelix 240/480 mg	Total
American Indian or Alaska Native	0	0	0
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	3	5
White	64	63	127
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight [1] [units: kilogram] Mean (Standard Deviation)	78.9 (12.9)	82.4 (13.4)	80.6 (13.2)
Body mass index [1] [units: kilogram per square meter] Mean (Standard Deviation)	27 (4.0)	27.4 (3.4)	27.2 (3.7)
Curative intent [2] [units: participants]			
Yes	7	6	13
No	60	60	120
Gleason Score [3] [units: participants]			
2-4	8	3	11
5-6	19	24	43
7-10	39	39	78
Data missing	1	0	1
Stage of Prostate Cancer [4] [units: participants]			
Localized	26	19	45
Locally advanced	17	22	39
Metastatic	14	16	30

	Degarelix 240/360 mg	Degarelix 240/480 mg	Total
Not classifiable	10	9	19
Time Since Prostate Cancer Diagnosis [units: days] Mean (Standard Deviation)	370 (1011)	265 (499)	319 (802)
Serum Testosterone [1] [units: ng/mL] Median (Full Range)	4.1 (2.0 to 10.4)	4.1 (1.6 to 9.1)	4.1 (1.6 to 10.4)
Serum PSA [1] [units: ng/mL] Median (Full Range)	22.9 (2.1 to 5309.6)	18.2 (0.5 to 2668.4)	20.3 (0.5 to 5309.6)
Serum FSH [units: IU/L] Median (Full Range)	8.4 (2.2 to 39.8)	6.9 (1.6 to 52.2)	7.0 (1.6 to 56.2)
Serum LH [units: IU/L] Median (Full Range)	5.9 (1.4 to 14.0)	4.6 (1.9 to 34.0)	5.3 (1.4 to 34.0)

[1] ITT population.

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

[3] 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.

Gleason score for 1 patient is missing

[4] 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	Probability of Testosterone at Castration Level (≤0.5 ng/mL) From Day 28 Through Day 364
Measure Description	Kaplan-Maier estimates of the cumulative probabilities of testosterone <=0.5 ng/mL from Day 28 to Day 364.
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Probability of Testosterone at Castration Level (≤0.5 ng/mL) From Day 28 Through Day 364 [units: percentage of participants] Mean (95% Confidence Interval)	89.0 (78.3 to 94.6)	93.3 (83.1 to 97.4)

2. Secondary Outcome Measure:

Measure Title	Serum Levels of Testosterone Over Time
Measure Description	
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Serum Levels of Testosterone Over Time [units: ng/mL] Median (Full Range)		
Day 28	0.1 (0 to 0.5)	0.1 (0 to 4.6)
Day 84	0.1 (0 to 0.4)	0.1 (0 to 1.1)
Day 364	0.1 (0 to 2.4)	0.1 (0 to 0.7)

3. Secondary Outcome Measure:

Measure Title	Probability of Testosterone at Castration Level (≤0.5 ng/mL) From Day 56 Through Day 364
Measure Description	Kaplan-Maier estimates of the cumulative probabilities of testosterone <=0.5 ng/mL from Day 56 to Day 364.
Time Frame	1 year
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Probability of Testosterone at Castration Level (≤0.5 ng/mL) From Day 56 Through Day 364 [units: percentage of participants] Mean (95% Confidence Interval)	89.0 (78.3 to 94.6)	93.3 (83.0 to 97.4)

4. Secondary Outcome Measure:

Measure Title	Probability of no PSA Failure
Measure Description	Cumulative probability (%) and 95% confidence interval (CI) for completing the study without PSA failure. PSA failure was defined as two consecutive increases of 50%, and at least 5 ng/mL, compared to nadir (lowest level of PSA achieved).
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Probability of no PSA Failure [units: percentage of participants] Mean (95% Confidence Interval)	93.5 (83.6 to 97.5)	94.6 (84.3 to 98.2)

5. Secondary Outcome Measure:

Measure Title	Serum Levels of PSA Over Time
Measure Description	
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Serum Levels of PSA Over Time [units: ng/mL] Median (Full Range)		
Day 28	3.5 (0 to 274.6)	3.1 (0.2 to 91.3)
Day 84	1.2 (0 to 37.2)	1.2 (0 to 47.4)
Day 364	0.4 (0 to 354.4)	0.7 (0 to 135.5)

6. Secondary Outcome Measure:

Measure Title	Serum Levels of Follicle Stimulating Hormone (FSH) Over Time
Measure Description	
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

	Description
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Serum Levels of Follicle Stimulating Hormone (FSH) Over Time [units: IU/L] Median (Full Range)		
Day 28	0.3 (0.2 to 3.2)	0.4 (0.2 to 8.1)
Day 84	0.6 (0.2 to 3.9)	0.5 (0.2 to 7.2)
Day 364	1.6 (0.2 to 7.9)	1.0 (0.2 to 9.2)

7. Secondary Outcome Measure:

Measure Title	Serum Levels of Luteinizing Hormone (LH) Over Time
Measure Description	
Time Frame	1 year
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Serum Levels of Luteinizing Hormone (LH) Over Time [units: IU/L] Median (Full Range)		
Day 28	0.1 (0 to 1.6)	0.1 (0 to 4.7)
Day 84	0.1 (0 to 1.4)	0.1 (0 to 2.5)
Day 364	0.3 (0 to 3.6)	0.2 (0 to 2.1)

8. Secondary 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 up to 1 year
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66
Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [units: participants]		

	Degarelix 240/360 mg	Degarelix 240/480 mg
Diastolic blood pressure <=50 and decrease >=15	0	0
Diastolic blood pressure >=105 and increase >=15	0	0
Systolic blood pressure <=90 and decrease >=20	0	0
Systolic blood pressure >=180 and increase >=20	1	1
Heart rate <=50 and decrease >=15	0	0
Heart rate >=120 and increase >=15	0	0
Body weight decrease of >=7 percent	6	0
Body weight increase of >=7 percent	8	4

9. 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	1 year
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Degarelix 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Measured Values

	Degarelix 240/360 mg	Degarelix 240/480 mg
Number of Participants Analyzed	67	66

	Degarelix 240/360 mg	Degarelix 240/480 mg
Liver Function Tests [units: participants]		
Abnormal alanine aminotransferase (ALAT)	22	21
Abnormal aspartate aminotransferase	33	23
Abnormal bilirubin	3	1
ALAT >3x upper limit of normal (ULN)	1	3
ALAT >3x ULN, bilirubin >1.5x ULN	0	0

Reported Adverse Events

Time Frame	1 year.
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 240/360 mg	Treatment group A: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 360 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.
Degarelix 240/480 mg	Treatment group B: Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 480 mg SC (by injection under the skin) given after 1, 4, 7, & 10 months.

Serious Adverse Events

	Degarelix 240/360 mg		Degarelix 240/480 mg	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	7/67 (10.45%)		11/66 (16.67%)	
Blood and lymphatic system disorders				
Anaemia [A] †	1/67 (1.49%)	2	0/66 (0%)	0
Iron Deficiency Anaemia [A] †	0/67 (0%)	0	1/66 (1.52%)	1

	Degarelix 240/360 mg		Degarelix 240/480 mg	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cardiac disorders				
Atrial fibrillation [A] †	1/67 (1.49%)	1	1/66 (1.52%)	1
Atrial flutter [A] †	1/67 (1.49%)	1	0/66 (0%)	0
Cardiac arrest [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Myocardial infarction [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Ventricular tachycardia [A] †	1/67 (1.49%)	1	0/66 (0%)	0
Gastrointestinal disorders				
Inguinal hernia [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Inguinal hernia strangulated [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Mechanical ileus [A] †	0/67 (0%)	0	1/66 (1.52%)	1
General disorders				
Death [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Hepatobiliary disorders				
Bile duct obstruction [A] †	1/67 (1.49%)	1	0/66 (0%)	0
Cholecystitis [A] †	1/67 (1.49%)	1	0/66 (0%)	0
Infections and infestations				
Bronchopneumonia [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Lyme disease [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Injury, poisoning and procedural complications				
Alcohol poisoning [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Metastases to bone [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Multiple myeloma [A] †	1/67 (1.49%)	1	0/66 (0%)	0

	Degarelix 240/360 mg		Degarelix 240/480 mg	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Nervous system disorders				
Depressed level of consciousness [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Syncope [A] †	1/67 (1.49%)	1	0/66 (0%)	0
Renal and urinary disorders				
Renal failure acute [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Tubulointerstitial nephritis [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Urinary retention [A] †	0/67 (0%)	0	1/66 (1.52%)	1
Vascular disorders				
Deep vein thrombosis [A] †	1/67 (1.49%)	1	0/66 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.1)

Other Adverse Events

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

	Degarelix 240/360 mg		Degarelix 240/480 mg	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	49/67 (73.13%)		53/66 (80.3%)	
General disorders				
Asthenia [A] †	4/67 (5.97%)	4	3/66 (4.55%)	3
Fatigue [A] †	2/67 (2.99%)	2	4/66 (6.06%)	4
Injection site erythema [A] †	4/67 (5.97%)	4	5/66 (7.58%)	10
Injection site pain [A] †	10/67 (14.93%)	19	13/66 (19.7%)	29
Pyrexia [A] †	0/67 (0%)	0	5/66 (7.58%)	5
Investigations				
Weight decreased [A] †	4/67 (5.97%)	4	2/66 (3.03%)	2

	Degarelix 240/360 mg		Degarelix 240/480 mg	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Weight increased [A] †	9/67 (13.43%)	9	5/66 (7.58%)	5
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	4/67 (5.97%)	4	2/66 (3.03%)	2
Reproductive system and breast disorders				
Gynaecomastia [A] †	4/67 (5.97%)	4	2/66 (3.03%)	2
Testicular atrophy [A] †	4/67 (5.97%)	4	4/66 (6.06%)	5
Vascular disorders				
Hot flush [A] †	24/67 (35.82%)	25	21/66 (31.82%)	23
Hypertension [A] †	6/67 (8.96%)	6	5/66 (7.58%)	5

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.1)

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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