ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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The Efficacy and Safety of Degarelix One Month Dosing Regimens in Prostate Cancer

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by (Responsible Party):	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00295750

Purpose

The study was a three-arm, active-control, multi-centre, parallel group study.

Condition	Intervention	Phase
Prostate Cancer	Drug: Degarelix Drug: Leuprolide 7.5 mg	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: An Open-label, Multi-Centre, Randomized, Parallel-group Study, Investigating the Efficacy and Safety of Degarelix One Month Dosing Regimens; 160 mg (40 mg/ml) and 80 mg (20mg/ml), in Comparison to LUPRON DEPOT® 7.5 mg in Patients With Prostate Cancer Requiring Androgen Ablation Therapy

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Percentage of Patients With Testosterone <=0.5ng/mL From Day 28 Through Day 364 [Time Frame: 12 months] [Designated as safety issue: No]
  Kaplan-Maier estimates of the cumulative probabilities of testosterone <=0.5 ng/mL from Day 28 to Day 364. The degarelix response rate estimation determined whether the lower bound of the 95% confidence interval for the cumulative probability of testosterone <=0.5 ng/mL from Day 28 to Day 364 was no lower than 90%.

Secondary Outcome Measures:

- Percentage of Patients With Testosterone Surge During the First Two Weeks of Treatment [Time Frame: 2 weeks] [Designated as safety issue: No]
  A patient was defined as having a testosterone surge if the testosterone level exceeded baseline by >=15% on any two days during the first two weeks of treatment (i.e. two of Study Days 1, 3, 7 and 14).
- Percentage of Patients With Testosterone Level <=0.5 ng/mL at Day 3 [Time Frame: 3 days] [Designated as safety issue: No]
  This outcome measure presents the testosterone levels 3 days after the initial dose of trial medication.
- Frequency and Size of Testosterone Changes at Day 255 and/or Day 259 Compared to the Testosterone Level at Day 252 [Time Frame: Day 252, Day 255, and Day 259] [Designated as safety issue: No]
  Testosterone increases on Day 255 and/or on Day 259 (highest value of Day 255 and Day 259 was used) were compared with Day 252 values. Patients were categorised with shifts of <=-0.25, >-0.25-0, >0-0.25, >0.25-0.5 and >0.5 ng/mL from mean testosterone levels on Day 252.
- Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28 [Time Frame: Days 14 and 28] [Designated as safety issue: No]
  Percentage change from Baseline to Day 14 and Day 28 in prostate-specific antigen, which is a clinically important biological marker for treatment effect and prostate cancer progression.
- Participants Grouped by Time to Prostate-specific Antigen Failure [Time Frame: 12 months] [Designated as safety issue: No]
  The time to prostate specific antigen failure was defined as the days from first dosing (scheduled dosing days) where an increase in serum prostate specific antigen of ≥50% from nadir and a least 5 ng/mL measured on two consecutive occasions at least two weeks apart was noted.
- Participants With Markedly Abnormal Change in Laboratory Variables (>=20 Percent of Patients) [Time Frame: Baseline to Day 364] [Designated as safety issue: No]
  Criteria for lab values changes from baseline to the end of the study considered markedly abnormal were set for each lab test. If 20% of patients reached that value, the results were reported.
- The Mean Value of QTc Interval as Measured by Electrocardiogram [Time Frame: 12 months] [Designated as safety issue: No]
  The QTc interval results are calculated with Fridericia's correction. QTc intervals are a standard evaluation of an electrocardiogram and help measure the risk of developing ventricular arrhythmias.
- Participants With Markedly Abnormal Change in Vital Signs and Body Weight [Time Frame: 12 months] [Designated as safety issue: No]
  Vital signs and body weight included incidence of markedly abnormal changes from baseline to the end of the study in blood pressure (systolic and diastolic), pulse, and body weight at the end of trial as compared to baseline. The table presents the number of patients in each group with normal baseline and markedly abnormal value post-baseline.

Enrollment: 620
Study Start Date: February 2006
Primary Completion Date: October 2007
Study Completion Date: October 2007

Arms	Assigned Interventions
Experimental: degarelix 240/160 mg Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.	Drug: Degarelix Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days for 364 days. Other Names: FE200486
Experimental: degarelix 240/80 mg	Drug: Degarelix

Arms	Assigned Interventions
Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days for 364 days. Other Names: FE 200486
Active Comparator: Leuprolide 7.5 mg Leuprolide (Lupron Depot) 7.5 mg IM (in the muscle) every 28 days starting at day 0.	Drug: Leuprolide 7.5 mg Leuprolide (Lupron Depot) 7.5mg IM (in the muscle every 28 days starting at day 0. Other Names: Lupron

Eligibility

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

Criteria

Main Inclusion Criteria:

- Patients, aged 18 years or over, with histologically proven prostate cancer of all stages in whom endocrine treatment is indicated.
- Baseline testosterone >1.5 ng/mL.
- Life expectancy of at least 12 months.

Contacts and Locations

Locations

United States, Alabama
Urology Centers of Alabama
Homewood, Alabama, United States, 35209
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
Pacific Clinical Center
Beverly Hills, California, United States, 90210
Simi-San Faernando Valley Urology Associates
Granada Hills, California, United States, 91344

South Orange County Medical Research Center
Laguna Woods,, California, United States, 92653
Western Clinical Research
Torrance, California, United States, 90505
United States, Colorado
Urology Associate PC
Denver, Colorado, United States, 80210
University of Colorado
Denver, Colorado, United States, 80262
United States, Florida
South Florida Medical Research
Aventura, Florida, United States, 33180
Florida Foundation for Healthcare Research
Ocala, Florida, United States, 34474
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Ocala, Florida, United States, 34474
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Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Results Publications:

Klotz L, Boccon-Gibod L, Shore ND, Andreou C, Persson BE, Cantor P, Jensen JK, Olesen TK, Schröder FH. The efficacy and safety of degarelix: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. BJU Int. 2008 Dec;102(11):1531-8. doi: 10.1111/j.1464-410X.2008.08183.x.

Responsible Party:	Ferring Pharmaceuticals
Study ID Numbers:	FE200486 CS21
Health Authority:	United States: Food and Drug Administration

Study Results

Participant Flow

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Overall Study

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Started	206 [1]	210 [1]	204 [1]
Intent-to-treat (ITT) Population	202 [2]	207 [2]	201 [2]
Completed	163	169	172
Not Completed	43	41	32
Adverse Event	19	15	12
Lack of Efficacy	1	1	0
Lost to Follow-up	1	4	1
Taking prohibited therapy	2	3	2

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Administrative errors	2	4	5
Trial drug errors	1	1	0
Disease progression	2	1	0
Personal reasons	0	1	0
Randomized but never received trial drug	4	3	3
Withdrawal by Subject	9	4	7
Protocol Violation	2	4	2

[1] randomized
[2] randomized and exposed patients

Baseline Characteristics

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Baseline Measures

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg	Total
Number of Participants	202	207	201	610
Age, Categorical [1] [units: participants]				
<=18 years	0	0	0	0
Between 18 and 65 years	37	43	38	118
>=65 years	165	164	163	492
Age, Continuous [2] [units: years] Median (Full Range)	72 (50 to 88)	72 (51 to 89)	74 (52 to 98)	73 (50 to 98)

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg	Total
Gender, Male/Female [2] [units: participants]				
Female	0	0	0	0
Male	202	207	201	610
Race (NIH/OMB) [3] [units: participants]				
American Indian or Alaska Native	22	18	19	59
Asian	1	1	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	11	17	10	38
White	168	171	172	511
More than one race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Region of Enrollment [3] [units: participants]				
North America	84	87	86	257
Europe	118	120	115	353
Curative Intent [4] [units: participants]				
Yes	24	30	24	78
No	178	177	177	532
Gleason Score [5] [units: participants]				
2-4	21	20	24	65
5-6	67	68	63	198
7	56	63	62	181
8-10	56	56	51	163

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg	Total
Stage of Prostate Cancer [6] [units: participants]				
Localized	59	69	63	191
Locally advanced	62	64	52	178
Metastatic	41	37	47	125
Not classifiable	40	37	39	116
Body Mass Index [3] [units: kilogram per square meter] Mean (Standard Deviation)	26.6 (3.70)	26.7 (4.21)	26.9 (3.86)	26.8 (3.93)
Serum Prostate-specific Antigen Levels [units: nanogram per milliliter] Median (Inter-Quartile Range)	19.9 (8.2 to 68)	19.8 (9.4 to 46)	19.0 (8.7 to 57)	19.0 (8.7 to 57)
Serum Testosterone Levels [units: nanogram per milliliter] Median (Inter-Quartile Range)	3.78 (2.86 to 5.05)	4.11 (3.05 to 5.32)	3.84 (2.91 to 5.01)	3.93 (2.89 to 5.10)
Time Since Prostate Cancer Diagnosis [2] [units: days] Mean (Standard Deviation)	485 (1109)	491 (994)	497 (1088)	491 (1063)
Weight [3] [units: kilogram] Mean (Standard Deviation)	78.7 (13.0)	79.8 (14.9)	79.4 (12.2)	79.3 (13.4)

[1] Intent-to-treat (ITT) population.

[2] ITT population.

[3] ITT population

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

[5] 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 scores were unavailable for 3 patients.

[6] 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	Percentage of Patients With Testosterone <=0.5ng/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. The degarelix response rate estimation determined whether the lower bound of the 95% confidence interval for the cumulative probability of testosterone <=0.5 ng/mL from Day 28 to Day 364 was no lower than 90%.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

Intent-to-treat (ITT) population.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Percentage of Patients With Testosterone <=0.5ng/mL From Day 28 Through Day 364 [units: percentage of patients] Mean (95% Confidence Interval)	98.3 (94.8 to 99.4)	97.2 (93.5 to 98.8)	96.4 (92.5 to 98.2)

Statistical Analysis 1 for Percentage of Patients With Testosterone <=0.5ng/mL From Day 28 Through Day 364

Statistical Analysis Overview	Comparison Groups	Degarelix 240/160 mg, Leuprolide 7.5 mg
	Comments	A non-inferiority assessment determined whether degarelix was non-inferior to leuprolide with respect to the cumulative probability of testosterone <=0.5 ng/mL from Day 28 to Day 364.

	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	The non-inferiority limit was -10 percentage points.

Method of Estimation	Estimation Parameter	Other [Difference in cumulative probability]
	Estimated Value	1.9
	Confidence Interval	(2-Sided) 97.5% -1.8 to 5.7
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Percentage of Patients With Testosterone <=0.5ng/mL From Day 28 Through Day 364

Statistical Analysis Overview	Comparison Groups	Degarelix 240/80 mg, Leuprolide 7.5 mg
	Comments	A non-inferiority assessment determined whether degarelix was non-inferior to leuprolide with respect to the cumulative probability of testosterone <=0.5 ng/mL from Day 28 to Day 364.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	The non-inferiority limit was -10 percentage points.

Method of Estimation	Estimation Parameter	Other [Difference in cumulative probability]
	Estimated Value	0.9
	Confidence Interval	(2-Sided) 97.5% -3.2 to 5.0
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Patients With Testosterone Surge During the First Two Weeks of Treatment
Measure Description	A patient was defined as having a testosterone surge if the testosterone level exceeded baseline by >=15% on any two days during the first two weeks of treatment (i.e. two of Study Days 1, 3, 7 and 14).
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

ITT population. If one or more of the testosterone values on Days 1, 3, 7 or 14 was missing, the last observation was carried forward.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Percentage of Patients With Testosterone Surge During the First Two Weeks of Treatment [units: percentage of patients] Mean (95% Confidence Interval)	0.5 (0.0 to 2.7)	0.0 (0.0 to 1.8)	80.1 (73.9 to 85.4)

Statistical Analysis 1 for Percentage of Patients With Testosterone Surge During the First Two Weeks of Treatment

Statistical Analysis Overview	Comparison Groups	Degarelix 240/160 mg, Leuprolide 7.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Percentage of Patients With Testosterone Surge During the First Two Weeks of Treatment

Statistical Analysis Overview	Comparison Groups	Degarelix 240/80 mg, Leuprolide 7.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Percentage of Patients With Testosterone Level <=0.5 ng/mL at Day 3
Measure Description	This outcome measure presents the testosterone levels 3 days after the initial dose of trial medication.
Time Frame	3 days
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Percentage of Patients With Testosterone Level <=0.5 ng/mL at Day 3 [units: percentage of patients] Mean (95% Confidence Interval)	95.5 (91.7 to 97.9)	96.1 (92.5 to 98.3)	0 (0 to 1.8)

Statistical Analysis 1 for Percentage of Patients With Testosterone Level <=0.5 ng/mL at Day 3

Statistical Analysis Overview	Comparison Groups	Degarelix 240/160 mg, Leuprolide 7.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Percentage of Patients With Testosterone Level <=0.5 ng/mL at Day 3

Statistical Analysis Overview	Comparison Groups	Degarelix 240/80 mg, Leuprolide 7.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Frequency and Size of Testosterone Changes at Day 255 and/or Day 259 Compared to the Testosterone Level at Day 252
Measure Description	Testosterone increases on Day 255 and/or on Day 259 (highest value of Day 255 and Day 259 was used) were compared with Day 252 values. Patients were categorised with shifts of <=-0.25, >-0.25-0, >0-0.25, >0.25-0.5 and >0.5 ng/mL from mean testosterone levels on Day 252.
Time Frame	Day 252, Day 255, and Day 259
Safety Issue?	No

Analysis Population Description

ITT population who had blood samples drawn on Day 252, Day 255, and Day 259.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	176	178	179
Frequency and Size of Testosterone Changes at Day 255 and/or Day 259 Compared to the Testosterone Level at Day 252 [units: participants]			
<=-0.25 ng/mL	1	3	0
>-0.25-0 ng/mL	84	85	49
>0-0.25 ng/mL	91	90	122
>0.25-0.5 ng/mL	0	0	5
>0.5 ng/mL	0	0	3

5. Secondary Outcome Measure:

Measure Title	Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28
Measure Description	Percentage change from Baseline to Day 14 and Day 28 in prostate-specific antigen, which is a clinically important biological marker for treatment effect and prostate cancer progression.
Time Frame	Days 14 and 28
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28 [units: percent change] Median (Inter-Quartile Range)			
Day 14	-64.6 (-77.8 to -40.8)	-63.4 (-77.1 to -48.4)	-17.9 (-35.5 to -5.2)
Day 28	-82.3 (-91.4 to -68.3)	-84.9 (-91.6 to -73.2)	-66.7 (-81.3 to -47.7)

Statistical Analysis 1 for Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240/160 mg, Leuprolide 7.5 mg
	Comments	Percentage change from baseline to Day 14
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 2 for Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240/80 mg, Leuprolide 7.5 mg
	Comments	Percentage change from baseline to Day 14
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 3 for Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240/160 mg, Leuprolide 7.5 mg
	Comments	Percentage change from baseline to Day 28
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 4 for Percentage Change in Prostate-specific Antigen From Baseline to Day 14 and Day 28

Statistical Analysis Overview	Comparison Groups	Degarelix 240/80 mg, Leuprolide 7.5 mg
	Comments	Percentage change from baseline to Day 28
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]

	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Participants Grouped by Time to Prostate-specific Antigen Failure
Measure Description	The time to prostate specific antigen failure was defined as the days from first dosing (scheduled dosing days) where an increase in serum prostate specific antigen of ≥50% from nadir and a least 5 ng/mL measured on two consecutive occasions at least two weeks apart was noted.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

ITT population. Missing values were not imputed for this endpoint. Number in table represents the number of patients with prostate-specific antigen failure.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Participants Grouped by Time to Prostate-specific Antigen Failure [units: participants]			
Day 0-28 (patients at risk=193, 201, 194)	1	0	1
Day 0-56 (patients at risk=192, 197, 192)	1	0	1
Day 0-84 (patients at risk=190, 193, 190)	1	0	1
Day 0-112 (patients at risk=190, 189, 188)	1	1	3
Day 0-140 (patients at risk=187, 187, 182)	2	2	7

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Day 0-168 (patients at risk=179, 185, 180)	7	4	9
Day 0-196 (patients at risk=173, 181, 175)	11	4	11
Day 0-224 (patients at risk=168, 175, 173)	14	7	12
Day 0-252 (patients at risk=165, 169, 168)	16	9	14
Day 0-280 (patients at risk=157, 165, 163)	20	11	18
Day 0-308 (patients at risk=153, 161, 156)	23	12	21
Day 0-336 (patients at risk=149, 156, 150)	26	15	24
Day 0-364 (patients at risk=149, 155, 148)	26	16	26

Statistical Analysis 1 for Participants Grouped by Time to Prostate-specific Antigen Failure

Statistical Analysis Overview	Comparison Groups	Degarelix 240/160 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Cumulative probability]
	Estimated Value	85.8
	Confidence Interval	(2-Sided) 95% 79.8 to 90.1
	Estimation Comments	95% confidence interval for the cumulative probability of completing the study without prostate specific antigen failure from Day 0 to Day 364.

Statistical Analysis 2 for Participants Grouped by Time to Prostate-specific Antigen Failure

Statistical Analysis Overview	Comparison Groups	Degarelix 240/80 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Cumulative probability]
	Estimated Value	91.1
	Confidence Interval	(2-Sided) 95% 85.9 to 94.5
	Estimation Comments	95% confidence interval for the cumulative probability of completing the study without prostate specific antigen failure from Day 0 to Day 364.

Statistical Analysis 3 for Participants Grouped by Time to Prostate-specific Antigen Failure

Statistical Analysis Overview	Comparison Groups	Leuprolide 7.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Cumulative probability]
	Estimated Value	85.9
	Confidence Interval	(2-Sided) 95% 79.9 to 90.2
	Estimation Comments	95% confidence interval for the cumulative probability of completing the study without prostate specific antigen failure from Day 0 to Day 364.

7. Secondary Outcome Measure:

Measure Title	Participants With Markedly Abnormal Change in Laboratory Variables (>=20 Percent of Patients)
Measure Description	Criteria for lab values changes from baseline to the end of the study considered markedly abnormal were set for each lab test. If 20% of patients reached that value, the results were reported.
Time Frame	Baseline to Day 364
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Participants With Markedly Abnormal Change in Laboratory Variables (>=20 Percent of Patients) [units: participants]			
Haematocrit (<=0.37 ratio)	73	80	73
Haemoglobin (<=115 g/L)	32	45	38
Serum Urea Nitrogen (>=10.7 mmol/L)	48	41	50
Urine Protein (>=2 units from baseline)	65	64	63
Urine Bacteria (0 at baseline and >0 on treatment)	96	105	107

8. Secondary Outcome Measure:

Measure Title	The Mean Value of QTc Interval as Measured by Electrocardiogram
Measure Description	The QTc interval results are calculated with Fridericia's correction. QTc intervals are a standard evaluation of an electrocardiogram and help measure the risk of developing ventricular arrhythmias.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

ITT population. End of Study values obtained at day 364 (+-7 days) for patients who completed. Patients who withdrew early had variable timeframes for the end of study value.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
The Mean Value of QTc Interval as Measured by Electrocardiogram [units: milliseconds] Mean (Standard Deviation)			
Baseline Day 0 (n=202, 207, 201)	403 (20.2)	407 (21.6)	404 (19.4)
Day 3 (n=195, 204, 197)	404 (22.1)	411 (23.5)	405 (23.0)
End of study 12 months (n=202, 207, 201)	415 (21.7)	420 (22.3)	419 (23.3)

9. Secondary Outcome Measure:

Measure Title	Participants With Markedly Abnormal Change in Vital Signs and Body Weight
Measure Description	Vital signs and body weight included incidence of markedly abnormal changes from baseline to the end of the study in blood pressure (systolic and diastolic), pulse, and body weight at the end of trial as compared to baseline. The table presents the number of patients in each group with normal baseline and markedly abnormal value post-baseline.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

ITT population. The first value in the category represents the actual clinical reading and the second is the change from baseline for blood pressure (units: millimeters of mercury) and heart rate (units:beats per minute). The weight category includes patients whose percent weight change from baseline fit the stated ranges.

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Measured Values

	Degarelix 240/160 mg	Degarelix 240/80 mg	Leuprolide 7.5 mg
Number of Participants Analyzed	202	207	201
Participants With Markedly Abnormal Change in Vital Signs and Body Weight [units: participants]			
Systolic blood pressure <=90 and decrease >=20	12	8	6
Systolic blood pressure >=180 and increase >=20	20	16	23
Diastolic blood pressure <=50 and decrease >=15	12	10	9
Diastolic blood pressure >=105 and increase >=15	5	13	8
Heart rate <=50 and decrease >=15	8	7	9
Heart rate >=120 and increase >=15	1	0	1
Body weight decrease of >=7 percent	5	6	10
Body weight increase of >=7 percent	24	15	23

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Degarelix 240/160 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 160 mg SC (by injection under the skin) given every 28 days.
Degarelix 240/80 mg	Initial dose of 240 mg SC (by injection under the skin) on day 0. Maintenance dose of 80 mg SC (by injection under the skin) given every 28 days.
Leuprolide 7.5 mg	Lupron Depot 7.5 mg IM (in the muscle) every 28 days starting at day 0.

Serious Adverse Events

	Degarelix 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	24/		21/		28/	
Blood and lymphatic system disorders						
Anaemia [A] †	2/202 (0.99%)	2	0/207 (0%)	0	3/201 (1.49%)	3
Iron deficiency anaemia [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Cardiac disorders						
Acute coronary syndrome [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Acute myocardial infarction [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Angina unstable [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Bradycardia [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Cardiac arrest [A] †	0/202 (0%)	0	2/207 (0.97%)	2	0/201 (0%)	0
Cardiac disorder [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Cardiac failure [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Cardiac failure congestive [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Cardiopulmonary failure [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Cardiovascular disorder [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Coronary artery disease [A] †	0/202 (0%)	0	1/207 (0.48%)	1	1/201 (0.5%)	1

	Degarelix 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Myocardial infarction [A] †	0/202 (0%)	0	1/207 (0.48%)	1	2/201 (1%)	2
Myocardial ischaemia [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Myopericarditis [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Eye disorders						
Cataract [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Gastrointestinal disorders						
Duodenal ulcer haemorrhage [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Gastric haemorrhage [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Gastric ulcer haemorrhage [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Gastritis [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Gastrointestinal haemorrhage [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Inguinal hernia [A] †	1/202 (0.5%)	1	1/207 (0.48%)	1	0/201 (0%)	0
Inguinal hernia, obstructive [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Large intestinal obstruction [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Pancreatitis acute [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Peritonitis [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
General disorders						
Non-cardiac chest pain [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Pyrexia [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Hepatobiliary disorders						
Cholecystitis acute [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Hepatic failure [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1

	Degarelix 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Hepatomegaly [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Infections and infestations						
Bronchopneumonia [A] †	1/202 (0.5%)	1	1/207 (0.48%)	1	0/201 (0%)	0
Ear infection [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Gastroenteritis [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Lobar pneumonia [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Pneumonia [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Post procedural cellulitis [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Injury, poisoning and procedural complications						
Compression fracture [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Femoral neck fracture [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Hip fracture [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Overdose [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Spinal compression fracture [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Investigations						
Blood creatinine increased [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Electrocardiogram (ECG) signs of myocardial ischaemia [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Prostate examination abnormal [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Metabolism and nutrition disorders						
Dehydration [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Diabetes mellitus [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Musculoskeletal and connective tissue disorders						

	Degarelix 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Pathological fracture [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Spinal column stenosis [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Gallbladder cancer [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Linitis plastica [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Malignant lymphoma unclassifiable [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Malignant melanoma [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Metastases to bone [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Metastases to liver [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Metastases to lung [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Pleural mesothelioma malignant [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Prostate cancer [A] †	1/202 (0.5%)	1	1/207 (0.48%)	1	1/201 (0.5%)	1
Prostate cancer metastatic [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Squamous cell carcinoma [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Nervous system disorders						
Cerebral infarction [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Cerebrovascular accident [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Cerebrovascular insufficiency [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Hyperkinesia [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Ruptured cerebral aneurysm [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Syncope [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Renal and urinary disorders						

	Degarelix 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Bladder obstruction [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Calculus bladder [A] †	1/202 (0.5%)	1	1/207 (0.48%)	1	0/201 (0%)	0
Calculus ureteric [A] †	0/202 (0%)	0	2/207 (0.97%)	2	1/201 (0.5%)	1
Haematuria [A] †	2/202 (0.99%)	2	1/207 (0.48%)	1	0/201 (0%)	0
Hydronephrosis [A] †	1/202 (0.5%)	2	0/207 (0%)	0	1/201 (0.5%)	1
Renal failure [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Renal failure acute [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1
Renal failure chronic [A] †	1/202 (0.5%)	2	0/207 (0%)	0	0/201 (0%)	0
Urethral obstruction [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Urethral stenosis [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Urinary retention [A] †	2/202 (0.99%)	2	0/207 (0%)	0	2/201 (1%)	2
Respiratory, thoracic and mediastinal disorders						
Asthma [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Chronic obstructive pulmonary disease [A] †	1/202 (0.5%)	1	0/207 (0%)	0	0/201 (0%)	0
Orthopnoea [A] †	0/202 (0%)	0	0/207 (0%)	0	1/201 (0.5%)	1
Respiratory failure [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Vascular disorders						
Deep vein thrombosis [A] †	0/202 (0%)	0	0/207 (0%)	0	2/201 (1%)	3
Hypertension [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Hypotension [A] †	0/202 (0%)	0	1/207 (0.48%)	1	0/201 (0%)	0
Orthostatic hypotension [A] †	1/202 (0.5%)	1	0/207 (0%)	0	1/201 (0.5%)	1

† 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 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	165/		162/		153/	
Gastrointestinal disorders						
Constipation [A] †	6/202 (2.97%)	6	11/207 (5.31%)	12	10/201 (4.98%)	11
Nausea [A] †	11/202 (5.45%)	15	9/207 (4.35%)	10	8/201 (3.98%)	9
General disorders						
Chills [A] †	7/202 (3.47%)	9	11/207 (5.31%)	19	0/201 (0%)	0
Fatigue [A] †	13/202 (6.44%)	14	7/207 (3.38%)	11	13/201 (6.47%)	14
Injection site erythema [A] †	48/202 (23.76%)	63	36/207 (17.39%)	56	0/201 (0%)	0
Injection site induration [A] †	11/202 (5.45%)	14	8/207 (3.86%)	11	0/201 (0%)	0
Injection site nodule [A] †	13/202 (6.44%)	24	6/207 (2.9%)	8	0/201 (0%)	0
Injection site pain [A] †	61/202 (30.2%)	108	58/207 (28.02%)	114	1/201 (0.5%)	1
Injection site swelling [A] †	14/202 (6.93%)	23	13/207 (6.28%)	17	0/201 (0%)	0
Infections and infestations						
Urinary tract infection [A] †	3/202 (1.49%)	3	10/207 (4.83%)	14	18/201 (8.96%)	25
Investigations						
Alanine aminotransferase increased [A] †	17/202 (8.42%)	17	20/207 (9.66%)	22	11/201 (5.47%)	11

	Degarelix 240/160 mg		Degarelix 240/80 mg		Leuprolide 7.5 mg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Aspartate aminostransferase increased [A] †	10/202 (4.95%)	11	11/207 (5.31%)	12	6/201 (2.99%)	6
Weight increased [A] †	22/202 (10.89%)	22	18/207 (8.7%)	18	24/201 (11.94%)	24
Metabolism and nutrition disorders						
Hypercholesterolaemia [A] †	12/202 (5.94%)	12	7/207 (3.38%)	7	5/201 (2.49%)	5
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	6/202 (2.97%)	6	11/207 (5.31%)	12	18/201 (8.96%)	20
Back pain [A] †	12/202 (5.94%)	13	12/207 (5.8%)	12	17/201 (8.46%)	19
Vascular disorders						
Hot flush [A] †	53/202 (26.24%)	59	53/207 (25.6%)	71	43/201 (21.39%)	50
Hypertension [A] †	14/202 (6.93%)	16	11/207 (5.31%)	12	8/201 (3.98%)	8

† 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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