ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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A Long-term Extension Study Evaluating a One-Month Dosing Regimen of Degarelix in Prostate Cancer Requiring Androgen Ablation Therapy

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by (Responsible Party):	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00451958

Purpose

Participants who completed the FE200486 CS21 study (NCT00295750) could enter the FE200486 CS21A study. The study continued until all non-discontinued participants had received treatment for at least 5 years.

Condition	Intervention	Phase
Prostate Cancer	Drug: Degarelix 80 mg / Degarelix 80 mg Drug: Degarelix 160 mg / Degarelix 160 mg Drug: Leuprolide 7.5 mg / Degarelix 80 mg Drug: Leuprolide 7.5 mg / Degarelix 160 mg	Phase 3

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

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [Time Frame: Up to 4 years of treatment] [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 (from main CS21 study, NCT00295750) and at least one post-baseline markedly abnormal value during CS21A.
- Number of Participants With Markedly Abnormal Values in Safety Laboratory Variables [Time Frame: Up to 4 years of treatment] [Designated as safety issue: No]
  This outcome measure included incidence of markedly abnormal changes in safety laboratory values. The table presents the number of participants with normal baseline (from main CS21 trial, NCT00295750) and at least one post-baseline markedly abnormal value during CS21A. Only the laboratory variables that had at least five percentages of participants in either group with abnormal value are presented, more variables were included in the study. ULN=Upper limit of normal.

Secondary Outcome Measures:

- Percentage of Participants With no Prostate-specific Antigen (PSA) Progression [Time Frame: Until all participants have received at least 5 years of treatment and at a frequency of every 3 months] [Designated as safety issue: No]
  PSA progression was defined as two consecutive increases of 50%, and at least 5 ng/mL, compared to nadir (obtained in either CS21, NCT00295750, or CS21A). The figures below present the percentage of participants with no PSA progression at each of the selected time points (there were more time points in the study) along with corresponding 95% confidence intervals (CI).
- Percentage of Participants With Testosterone Level Maintained at <=0.5 ng/mL From Day 28 in CS21 and Onwards [Time Frame: Until all participants have received at least 5 years of treatment and at a frequency of every 6 months] [Designated as safety issue: No]
  The results below present the percentage of participants of having testosterone <=0.5 ng/mL at each of the selected time points (there were more time points in the study) from Day 28 in CS21 (NCT00295750) until the end of the CS21A study. In all treatment groups approximately 3% per year of the participants had at least one testosterone >0.5 ng/mL during the study.
- Serum Levels of Testosterone From the Time of Switch From Leuprolide to Degarelix up to Day 56 [Time Frame: From time of switch to Day 56] [Designated as safety issue: No]
- Serum Levels of PSA From the Time of Switch From Leuprolide to Degarelix to Day 56 [Time Frame: From time of switch to Day 56] [Designated as safety issue: No]
- Serum Levels of Luteinizing Hormone (LH) From the Time of Switch From Leuprolide to Degarelix to Day 56 [Time Frame: From time of switch to Day 56] [Designated as safety issue: No]
- Serum Levels of Follicle Stimulating Hormone (FSH) From the Time of Switch From Leuprolide to Degarelix to Day 56 [Time Frame: From time of switch to Day 56] [Designated as safety issue: No]

Enrollment: 386
Study Start Date: March 2007
Primary Completion Date: October 2011
Study Completion Date: December 2011

Arms	Assigned Interventions
Experimental: Degarelix 80 mg / Degarelix 80 mg The degarelix doses were administered into the abdominal wall every 28 days.	Drug: Degarelix 80 mg / Degarelix 80 mg Other Names: Firmagon

Arms	Assigned Interventions
A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.	
Experimental: Degarelix 160 mg / Degarelix 160 mg The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.	Drug: Degarelix 160 mg / Degarelix 160 mg Other Names: Firmagon
Experimental: Leuprolide 7.5 mg / Degarelix 80 mg During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study.	Drug: Leuprolide 7.5 mg / Degarelix 80 mg Other Names: Firmagon Lupron

Arms	Assigned Interventions
Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.	
Experimental: Leuprolide 7.5 mg / Degarelix 160 mg During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.	Drug: Leuprolide 7.5 mg / Degarelix 160 mg Other Names: Firmagon Lupron

Eligibility

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

Criteria

Inclusion/Exclusion Criteria:

- Patients with histologically proven prostate cancer of all stages in whom endocrine treatment is indicated.
- Signed informed consent
- The patients must have completed the FE 200486 CS21 Study.

Contacts and Locations

Locations

- United States, Alabama
  - Urology Centers Of Alabama
    - Homewood, Alabama, United States
- United States, California
  - South Orange County Medical Research Center
    - Laguna Hills, California, United States
  - Western Clinical Research
    - Torrance, California, United States
- United States, Colorado
  - Urology Associates Research
    - Englewood, Colorado, United States
- United States, Florida
  - South Florida Medical Research
    - Aventura, Florida, United States
  - Investigational Site
    - Ocala, Florida, United States
- United States, Louisiana
  - Regional Urology
    - Shreveport, Louisiana, United States
- United States, New Jersey
  - Lawrenceville Urology
    - Lawrenceville, New Jersey, United States
- United States, New York
  - Investigational Site
    - Carmel, New York, United States
- United States, North Carolina
  - North Urology Research
    - Concord, North Carolina, United States
  - Investigational Site
    - Greensboro, North Carolina, United States
- United States, Pennsylvania
  - State College Urologic Association
    - State College, Pennsylvania, United States
- United States, Texas
  - Urology San Antonio Research
    - San Antonio, Texas, United States
- United States, Washington
  - Seattle Urology Research Center
    - Burien, Washington, United States
- Canada
  - Can-Med Clinical Research Inc

Victoria, Canada
Canada, Nova Scotia
Investigational Site
Kentville, Nova Scotia, Canada
Canada, Ontario
The Female/Male Health Centres
Barrie, Ontario, Canada
Brantford Urology Research
Brantford, Ontario, Canada
Burlington Professional Centre
Burlington, Ontario, Canada
The Urology Research Centre
Burlington, Ontario, Canada
Investigational Site
Newmarket, Ontario, Canada
The Female/Male Health Centres
Oakville, Ontario, Canada
Canada, Quebec
Urology South Shore Research
Greenfields, Quebec, Canada
Czech Republic
Urocentrum Brno
Brno, Czech Republic
UROHELP - Bozetechova
Brno, Czech Republic
Nemocnice Jindrichuv Hradec, a.s.
Jindrichuv Hradec, Czech Republic
Fakultni Nemocnice Olomouc
Olomouc, Czech Republic
Slezska nemocnice
Opava, Czech Republic
Vseobecna fakultni nemocnice v Praze, Prague2
Prague, Czech Republic
Fakultni nemocnice v Motole, Prague5
Prague, Czech Republic
Fakultni nemocnice v Motole, Prague5
Prague, Czech Republic
Germany
Klinikum Mannheim Universitätsklinikum GmbH
Mannheim, Germany
Klinikum Mannheim Universitätsklinikum GmbH
Mannheim, Germany
Klinikum Mannheim Universitätsklinikum GmbH
Mannheim, Germany
Klinikum der Universität Regensburg

Regensburg, Germany
Klinikum der Universität Regensburg
Regensburg, Germany
Hungary
Fővárosi Önkormányzat uzsoki utcai Kórház
Budapest, Hungary
Dombóvári Szent Lukács Egészségügyi Kht.
Dombóvár, Hungary
Petz Aladár Megyei Oktató Kórház
Győr, Hungary
Borsod-Abaúj-Zemplén Megyei Kórház és Egyetemi Oktató Kórház
Miskolc, Hungary
Miskolci Semmelweis Ignác Egészségügyi Központ és Egyetemi Oktató Kórház Nonprofit Kft
Miskolc, Hungary
Pécsi Tudományegyetem
Pécs, Hungary
Investigational Site
Szeged, Hungary
Mexico
Investigational Site
Acapulco, Mexico
Hospital Christus Muguerza del Parque
Chihuahua, Chih., Mexico
Investigational Sit
Durango, Mexico
Hospital Aranda de la Parra , S.A. de C.V.
Leon, GTO, Mexico
Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran Mexico, DF Mexico
Mexico, DF, Mexico
Investigational Site
Mexico, DF, Mexico
Investigational Site
Zapopan, Jalisco, Mexico
Consultorio Medico
Zapopan, Jalisco, Mexico
Netherlands
Investigational Site
Ede, Netherlands
Investigational Site
Eindhoven, Netherlands
Atrium MC
Heerlen, Netherlands
Puerto Rico
Hospital Andres Grillasca
Ponce, Puerto Rico

Romania
Investigational Site
Arad, Romania
Investigational Site
Bucharest, Romania
Sfantul Ioan" Emergency Clinical Hospital
Bucharest, Romania
Fundeni Uronephrology and Renal Transplant Clinical Institute
Bucharest, Romania
PROVITA 2000 Medical Center
Constanta, Romania
Investigational Site
Iasi, Romania
Sibiu Emergency Clinical County Hospital
Sibiu, Romania
Russian Federation
City Clinical Hospital #1 n.a. N.I.Pirogov
Moscow, Russian Federation
Moscow State University of Medicine and Dentistry
Moscow, Russian Federation
City Clinical Hospital #60
Moscow, Russian Federation
Investigational Site
St. Petersburg, Russian Federation
St.Petersburg State Medical Academy n. a. I.I.Mechnikov
St. Petersburg, Russian Federation
City Pokrovskaya Hospital
St. Petersburg, Russian Federation
Ukraine
Dnipropetrovsk State Medical Academy
Dnipropetrovsk, Ukraine
Regional Clinical Center of Urology and Nephrology n.a. V.I.Shapoval
Kharkiv, Ukraine
Kyiv City Clinical Hospital #3
Kyiv, Ukraine
Odesa State Medical University
Odesa, Ukraine
United Kingdom
Clatterbridge Centre For Oncology
Bebington, Wirral, United Kingdom

Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals
Study ID Numbers:	FE200486 CS21A
	2006-006913-34 [EudraCT Number]
Health Authority:	United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details	All participants who completed the CS21 study (NCT00295750) were eligible to enrol into the CS21A extension study. Since the number of participants who completed this long-term study was low, no firm conclusions can be drawn from the results.
Pre-Assignment Details	Initially, participants treated with degarelix during CS21 continued to treatment and patients who received treatment with leuprolide during CS21 were re-randomised to one of the two degarelix treatment regimens. Following a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg for the rest of the study.

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 of the CS21 study (NCT00295750) as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the CS21 study and the current CS21A study.
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 of the CS21 study (NCT00295750) as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the CS21 study and the current CS21A study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

	Description
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study (NCT00295750), leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study (NCT00295750), leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg	During the main CS21 study (NCT00295750), leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. When the main CS21 study was completed these patients were switched to treatment with degarelix 80 mg or 160 mg in the CS21A study.

CS21 (NCT00295750)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg	Leuprolide 7.5 mg
Started	210 [1]	206 [2]	0 [3]	0 [3]	204
Completed	169	163	0	0	172
Not Completed	41	43	0	0	32

[1] CS21 intention-to-treat (ITT) population.
[2] CS21 ITT population.
[3] Participants were switched from the leuprolide 7.5 mg group when CS21 was completed.

CS21A (NCT00451958)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg	Leuprolide 7.5 mg
Started	125 [1]	126 [2]	69 [2]	66 [3]	0 [4]
Completed	60	49	27	27	0
Not Completed	65	77	42	39	0
Adverse Event	21	34	14	17	0
Lost to Follow-up	6	5	1	1	0
Protocol Violation	1	3	2	0	0
Physician Decision	2	4	4	4	0
Withdrawal by Subject	7	4	4	3	0
Miscellaneous reasons	28	27	17	14	0

[1] CS21A intention-to-treat (ITT) population.
[2] CS21A ITT population.
[3] One of the enrolled participants never received any treatment, i.e. the CS21A ITT population=65.
[4] Participants were switched to the degarelix groups when CS21 was completed.

Baseline Characteristics

Analysis Population Description
CS21A intention-to-treat (ITT) population.

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.

	Description
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Baseline Measures

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg	Total
Number of Participants	125	126	69	65	385
Age, Continuous [1] [units: years] Mean (Standard Deviation)	70.1 (7.62)	71.1 (8.25)	72.4 (9.46)	71.4 (8.24)	71.1 (8.29)
Gender, Male/Female [2] [units: participants]					
Female	0	0	0	0	0

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg	Total
Male	125	126	69	65	385
Region of Enrollment [2] [units: participants]					
United States	12	14	13	9	48
Hungary	7	9	5	5	26
Czech Republic	11	12	6	8	37
Mexico	15	17	10	7	49
Canada	4	5	5	4	18
Ukraine	11	10	7	3	31
Romania	36	39	16	15	106
Russian Federation	26	19	6	13	64
Netherlands	2	0	0	1	3
Germany	0	0	1	0	1
United Kingdom	1	1	0	0	2
Body Weight [2] [units: kilogram] Mean (Standard Deviation)	78.4 (12.6)	79.2 (13.4)	78.7 (11.3)	80.0 (12.1)	79.0 (12.5)
Body Mass Index [2] [units: kilogram per square meter] Mean (Standard Deviation)	26.4 (3.92)	26.9 (3.79)	26.9 (3.94)	27.1 (3.67)	26.8 (3.84)
Gleason Score [3] [units: participants]					
Gleason Score 2-4	15	17	8	11	51
Gleason Score 5-6	37	44	25	18	124
Gleason Score 7-10	73	63	36	36	208
Stage of Prostate Cancer [4] [units: participants]					
Localised	39	36	20	19	114
Locally advanced	46	44	18	24	132

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg	Total
Metastatic	23	22	21	9	75
Not classifiable	17	24	10	13	64
Serum Testosterone Levels [2] [units: nanograms per milliliter] Median (Full Range)	4.63 (1.28 to 10.6)	4.02 (0.55 to 10.6)	4.32 (1.34 to 12.5)	3.51 (0.37 to 8.00)	4.23 (0.37 to 12.5)
Serum Prostate-Specific Antigen (PSA) Levels [2] [units: nanograms per milliliter] Median (Full Range)	22.2 (1.70 to 3187)	22.5 (1.50 to 4902)	25.5 (1.60 to 2112)	14.0 (1.60 to 10952)	21.0 (1.50 to 10952)

[1] CS21A intention-to-treat (ITT) population.

[2] CS21A ITT population.

[3] CS21A 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. Two of the participants did not have a Gleason Score at Baseline.

[4] CS21A ITT population. Prostate cancer stage was classified according to the Tumor, Nodes, and Metastatic (TNM) scale to describe the extent of cancer. Localized refers to tumors without involvement of lymph nodes or metastasis. Advanced localized can be larger tumors that may involve the lymph nodes but no metastasis. Metastatic are more advanced cancers that are spreading beyond the original tumor.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight
Measure Description	This outcome measure included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight. The table presents the number of participants with normal baseline (from main CS21 study, NCT00295750) and at least one post-baseline markedly abnormal value during CS21A.
Time Frame	Up to 4 years of treatment
Safety Issue?	No

Analysis Population Description

The analysis population comprised all participants who were enrolled in the CS21A study and who received at least one dose of degarelix during the study period.

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
Number of Participants Analyzed	125	126	69	66
Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight				

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
[units: participants]				
Diastolic blood pressure <=50 and decrease >=15	3	6	3	6
Diastolic blood pressure >=105 and increase >=15	3	6	4	0
Systolic blood pressure <=90 and decrease >=20	4	4	5	3
Systolic blood pressure >=180 and increase >=20	7	13	7	4
Heart rate <=50 and decrease >=15	4	3	7	2
Heart rate >=120 and increase >=15	1	1	1	3
Body weight decrease of >=7 percent	15	24	21	8
Body weight increase of >=7 percent	25	14	4	5

2. Primary Outcome Measure:

Measure Title	Number of Participants With Markedly Abnormal Values in Safety Laboratory Variables
Measure Description	This outcome measure included incidence of markedly abnormal changes in safety laboratory values. The table presents the number of participants with normal baseline (from main CS21 trial, NCT00295750) and at least one post-baseline markedly abnormal value during CS21A. Only the laboratory variables that had at least five percentages of participants in either group with abnormal value are presented, more variables were included in the study. ULN=Upper limit of normal.
Time Frame	Up to 4 years of treatment
Safety Issue?	No

Analysis Population Description

The analysis population comprised all participants who were enrolled in the CS21A study and who received at least one dose of degarelix during the study period.

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.

	Description
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
Number of Participants Analyzed	125	126	69	65
Number of Participants With Markedly Abnormal Values in Safety Laboratory Variables [units: participants]				
S-Potassium (mmol/L) >=5.8	11	9	6	5
S-Alanine aminotransferase (IU/L) >3xULN	1	6	1	0

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
S-Alkaline phosphatase (IU/L) >3xULN+25% increase	4	5	4	2
S-Creatinine (µmol/L) >=177	12	7	5	2
S-Urea nitrogen (mmol/L) >=10.7	6	9	5	5
B-Haematocrit (Ratio) <=0.37	40	47	22	17
B-Haemoglobin (g/L) <=115	12	20	9	6
B-Red blood cell count (10^12/L) <=3.5	10	15	5	3
B-Eosinophils (%) >=10	6	7	1	1
B-Lymphocytes (%) <=10	8	9	10	5

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With no Prostate-specific Antigen (PSA) Progression
Measure Description	PSA progression was defined as two consecutive increases of 50%, and at least 5 ng/mL, compared to nadir (obtained in either CS21, NCT00295750, or CS21A). The figures below present the percentage of participants with no PSA progression at each of the selected time points (there were more time points in the study) along with corresponding 95% confidence intervals (CI).
Time Frame	Until all participants have received at least 5 years of treatment and at a frequency of every 3 months
Safety Issue?	No

Analysis Population Description

CS21 ITT analysis set i.e. all participants who received at least one dose of degarelix or leuprolide during the mail study (CS21).

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.

	Description
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
Number of Participants Analyzed	207	202	69	132
Percentage of Participants With no Prostate-specific Antigen (PSA) Progression [units: percentage of participants] Number (95% Confidence Interval)				
Day 28	100 (100 to 100)	99.5 (96.5 to 99.9)	98.6 (90.2 to 99.8)	100 (100 to 100)
Day 364	91.1 (85.9 to 94.5)	85.8 (79.8 to 90.1)	82.6 (71.4 to 89.7)	87.9 (80.4 to 92.7)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
Day 1960	61.0 (50.9 to 69.7)	58.7 (48.7 to 67.4)	50.7 (36.3 to 63.4)	73.8 (60.9 to 83.0)

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Testosterone Level Maintained at <=0.5 ng/mL From Day 28 in CS21 and Onwards
Measure Description	The results below present the percentage of participants of having testosterone <=0.5 ng/mL at each of the selected time points (there were more time points in the study) from Day 28 in CS21 (NCT00295750) until the end of the CS21A study. In all treatment groups approximately 3% per year of the participants had at least one testosterone >0.5 ng/mL during the study.
Time Frame	Until all participants have received at least 5 years of treatment and at a frequency of every 6 months
Safety Issue?	No

Analysis Population Description

CS21 ITT analysis set i.e. all participants who received at least one dose of degarelix or leuprolide during the mail CS21 study (NCT00295750).

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

	Description
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Leuprolide participants who dropped out during the first year (i.e. during CS21) were all attributed to what became the leuprolide 7.5 mg / degarelix 160 mg arm. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
Number of Participants Analyzed	206	197	69	128
Percentage of Participants With Testosterone Level Maintained at <=0.5 ng/mL From Day 28 in CS21 and Onwards [units: percentage] Number (95% Confidence Interval)				
Day 84	99.5 (96.5 to 99.9)	100 (100 to 100)	98.6 (90.2 to 99.8)	97.6 (92.7 to 99.2)
Day 364	97.2 (93.5 to 98.8)	98.3 (94.8 to 99.4)	97. (88.9 to 99.3)	96.0 (90.5 to 98.3)
Day 1876	82.0 (72.7 to 88.4)	87.7 (78.0 to 93.3)	84.1 (70.2 to 91.9)	88.4 (75.5 to 94.7)

5. Secondary Outcome Measure:

Measure Title	Serum Levels of Testosterone From the Time of Switch From Leuprolide to Degarelix up to Day 56
Measure Description	
Time Frame	From time of switch to Day 56
Safety Issue?	No

Analysis Population Description

All participants who received leuprolide in the main CS21 study (NCT00295750) and were switched over to degarelix in the CS21A extension study.

Reporting Groups

	Description
Leuprolide 7.5 mg/ Degarelix 240/80 mg	During the main CS21 study (NCT00295750), leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg/ Degarelix 240/160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Leuprolide 7.5 mg/ Degarelix 240/80 mg	Leuprolide 7.5 mg/ Degarelix 240/160 mg
Number of Participants Analyzed	69	64
Serum Levels of Testosterone From the Time of Switch From Leuprolide to Degarelix up to Day 56 [units: ng/mL]		

	Leuprolide 7.5 mg/ Degarelix 240/80 mg	Leuprolide 7.5 mg/ Degarelix 240/160 mg
Median (Full Range)		
Baseline	0.076 (0.015 to 1.36)	0.074 (0.015 to 0.229)
Day 3	0.084 (0.015 to 0.23)	0.068 (0.015 to 0.19)
Day 7	0.076 (0.015 to 0.22)	0.066 (0.015 to 0.16)
Day 14	0.085 (0.015 to 0.24)	0.073 (0.015 to 0.27)
Day 28	0.074 (0.015 to 0.21)	0.074 (0.015 to 0.19)
Day 56	0.080 (0.015 to 0.22)	0.077 (0.015 to 0.16)

6. Secondary Outcome Measure:

Measure Title	Serum Levels of PSA From the Time of Switch From Leuprolide to Degarelix to Day 56
Measure Description	
Time Frame	From time of switch to Day 56
Safety Issue?	No

Analysis Population Description

All participants who received leuprolide in the main CS21 study (NCT00295750) and were switched over to degarelix in the CS21A extension study.

Reporting Groups

	Description
Leuprolide 7.5 mg/ Degarelix 240/80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

	Description
Leuprolide 7.5 mg/ Degarelix 240/160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Leuprolide 7.5 mg/ Degarelix 240/80 mg	Leuprolide 7.5 mg/ Degarelix 240/160 mg
Number of Participants Analyzed	69	65
Serum Levels of PSA From the Time of Switch From Leuprolide to Degarelix to Day 56 [units: ng/mL] Median (Full Range)		
Baseline	0.4 (0 to 2938)	0.4 (0 to 1096)
Day 3	0.4 (0 to 754)	0.3 (0 to 1059)
Day 7	0.35 (0 to 724)	0.4 (0 to 1422)
Day 14	0.4 (0 to 671)	0.3 (0 to 1567)
Day 28	0.4 (0 to 441)	0.5 (0 to 2008)
Day 56	0.35 (0 to 620)	0.4 (0 to 1926)

7. Secondary Outcome Measure:

Measure Title	Serum Levels of Luteinizing Hormone (LH) From the Time of Switch From Leuprolide to Degarelix to Day 56
Measure Description	
Time Frame	From time of switch to Day 56
Safety Issue?	No

Analysis Population Description

All participants who received leuprolide in the main CS21 study (NCT00295750) and were switched over to degarelix in the CS21A extension study.

Reporting Groups

	Description
Leuprolide 7.5 mg/ Degarelix 240/80 mg	During the main CS21 study (NCT00295750), leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg/ Degarelix 240/160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Leuprolide 7.5 mg/ Degarelix 240/80 mg	Leuprolide 7.5 mg/ Degarelix 240/160 mg
Number of Participants Analyzed	69	65
Serum Levels of Luteinizing Hormone (LH) From the Time of Switch From Leuprolide to Degarelix to Day 56 [units: International units/Liter (IU/L)] Median (Full Range)		
Baseline	0.035 (0.035 to 1.12)	0.035 (0.035 to 0.40)
Day 3	0.035 (0.035 to 0.11)	0.035 (0.035 to 0.12)
Day 7	0.035 (0.035 to 0.11)	0.035 (0.035 to 0.08)
Day 14	0.035 (0.035 to 0.47)	0.035 (0.035 to 0.12)
Day 28	0.035 (0.035 to 0.16)	0.035 (0.035 to 0.19)
Day 56	0.035 (0.035 to 0.17)	0.035 (0.035 to 0.22)

8. Secondary Outcome Measure:

Measure Title	Serum Levels of Follicle Stimulating Hormone (FSH) From the Time of Switch From Leuprolide to Degarelix to Day 56
Measure Description	
Time Frame	From time of switch to Day 56
Safety Issue?	No

Analysis Population Description

All participants who received leuprolide in the main CS21 study (NCT00295750) and were switched over to degarelix in the CS21A extension study.

Reporting Groups

	Description
Leuprolide 7.5 mg/ Degarelix 240/80 mg	During the main CS21 study (NCT00295750), leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg/ Degarelix 240/160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Measured Values

	Leuprolide 7.5 mg/ Degarelix 240/80 mg	Leuprolide 7.5 mg/ Degarelix 240/160 mg
Number of Participants Analyzed	69	65

	Leuprolide 7.5 mg/ Degarelix 240/80 mg	Leuprolide 7.5 mg/ Degarelix 240/160 mg
Serum Levels of Follicle Stimulating Hormone (FSH) From the Time of Switch From Leuprolide to Degarelix to Day 56 [units: International units/Liter (IU/L)] Median (Full Range)		
Baseline	4.8 (1.2 to 15.8)	4.4 (1.5 to 12.2)
Day 3	2.7 (0.8 to 11.1)	2.8 (0.5 to 7.6)
Day 7	2.6 (0.7 to 11.8)	2.6 (0.4 to 6.9)
Day 14	2.2 (0.15 to 7.9)	2.3 (0.15 to 8.3)
Day 28	1.8 (0.15 to 7.6)	1.7 (0.15 to 6.7)
Day 56	1.3 (0.15 to 6.7)	1.55 (0.15 to 5.6)

Reported Adverse Events

Time Frame	From start of CS21A and up to 4.5 years.
Additional Description	The population comprised all participants who were enrolled into CS21A and who received at least one dose of degarelix during the study.

Reporting Groups

	Description
Degarelix 80 mg / Degarelix 80 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent doses of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days for the rest of the study.
Degarelix 160 mg / Degarelix 160 mg	The degarelix doses were administered into the abdominal wall every 28 days. A starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent monthly degarelix maintenance dose of 160 mg (40 mg/mL) degarelix were administered as single 4 mL s.c. injections every 28 days. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

	Description
Leuprolide 7.5 mg / Degarelix 80 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.
Leuprolide 7.5 mg / Degarelix 160 mg	During the main CS21 study, leuprolide (Lupron Depot) 7.5 mg was injected into the muscle every 28 days for one year. Starting one year after the first dose of leuprolide, degarelix doses were administered into the abdominal wall every 28 days. First, a starting dose of 240 mg (40 mg/mL) degarelix was administered as two 3 mL subcutaneous (s.c.) injections and one month later the participants received either subsequent monthly degarelix maintenance doses of 80 mg (20 mg/mL) or 160 mg (40 mg/mL) every 28 days for the rest of the study. Following the implementation of a protocol amendment, all patients received a monthly degarelix maintenance dose of 80 mg (20 mg/mL) for the rest of the study.

Serious Adverse Events

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	43/207 (20.77%)	60/202 (29.7%)	23/69 (33.33%)	22/66 (33.33%)
Blood and lymphatic system disorders				
Anaemia [A] †	1/207 (0.48%)	5/202 (2.48%)	1/69 (1.45%)	1/66 (1.52%)
Anaemia of malignant disease [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	1/66 (1.52%)
Iron deficiency anaemia [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Retroperitoneal lymphadenopathy [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Cardiac disorders				
Acute coronary syndrome [A] †	0/207 (0%)	1/202 (0.5%)	1/69 (1.45%)	0/66 (0%)
Acute myocardial infarction [A] †	2/207 (0.97%)	1/202 (0.5%)	0/69 (0%)	1/66 (1.52%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Angina pectoris [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Angina unstable [A] †	0/207 (0%)	2/202 (0.99%)	0/69 (0%)	1/66 (1.52%)
Atrial fibrillation [A] †	0/207 (0%)	0/202 (0%)	2/69 (2.9%)	0/66 (0%)
Atrioventricular block second degree [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Bradycardia [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cardiac arrest [A] †	2/207 (0.97%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cardiac failure [A] †	0/207 (0%)	2/202 (0.99%)	0/69 (0%)	0/66 (0%)
Cardiac failure congestive [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Cardio-respiratory arrest [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Cardiopulmonary failure [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Coronary artery disease [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	1/66 (1.52%)
Myocardial infarction [A] †	3/207 (1.45%)	1/202 (0.5%)	0/69 (0%)	2/66 (3.03%)
Myocardial ischaemia [A] †	1/207 (0.48%)	0/202 (0%)	1/69 (1.45%)	1/66 (1.52%)
Myopericarditis [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Eye disorders				
Retinal haemorrhage [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Gastrointestinal disorders				
Ascites [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Diverticular perforation [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Diverticulum intestinal haemorrhagic [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Faecaloma [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Gastric haemorrhage [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastric ulcer haemorrhage [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Gastritis [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Gastrointestinal haemorrhage [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Gastrooesophageal reflux disease [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Inguinal hernia [A] †	1/207 (0.48%)	2/202 (0.99%)	0/69 (0%)	0/66 (0%)
Inguinal hernia obstructive [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Nausea [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Oedematous pancreatitis [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Peritonitis [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Rectal stenosis [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Subileus [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Umbilical hernia [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
General disorders				
Accidental death [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Asthenia [A] †	0/207 (0%)	1/202 (0.5%)	2/69 (2.9%)	0/66 (0%)
Chest pain [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Death [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Disease progression [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Feeling abnormal [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Multi-organ failure [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Non-cardiac chest pain [A] †	0/207 (0%)	1/202 (0.5%)	1/69 (1.45%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Oedema peripheral [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Pyrexia [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Hepatobiliary disorders				
Bile duct stenosis [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Bile duct stone [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cholecystitis acute [A] †	2/207 (0.97%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Jaundice [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Infections and infestations				
Arthritis infective [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Bronchitis [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Bronchopneumonia [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cholecystitis infective [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Ear infection [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Empyema [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Gastroenteritis [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Injection site abscess [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Lobar pneumonia [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Pneumonia [A] †	2/207 (0.97%)	2/202 (0.99%)	0/69 (0%)	1/66 (1.52%)
Post procedural cellulitis [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Psoas abscess [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Scrotal gangrene [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Septic shock [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Injury, poisoning and procedural complications				
Alcohol poisoning [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Ankle fracture [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Compression fracture [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Femoral neck fracture [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Femur fracture [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	1/66 (1.52%)
Head injury [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Humerus fracture [A] †	1/207 (0.48%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Overdose [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Postoperative ileus [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Spinal compression fracture [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Investigations				
Blood creatinine increased [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
ECG signs of myocardial ischaemia [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Heart rate increased [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Prostate examination abnormal [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Metabolism and nutrition disorders				
Dehydration [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Diabetes mellitus [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	1/66 (1.52%)
Type 2 diabetes mellitus [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Musculoskeletal and connective tissue disorders				
Back pain [A] †	0/207 (0%)	0/202 (0%)	2/69 (2.9%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Groin pain [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Intervertebral disc protrusion [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Osteoarthritis [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Pathological fracture [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Spinal column stenosis [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Bile duct cancer [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Bladder cancer [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Bladder cancer recurrent [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Bladder papilloma [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Colon cancer [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Colon cancer stage II [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Gastric neoplasm [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Lung neoplasm [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Malignant lymphoma unclassifiable high grade [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Malignant melanoma [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Metastases to biliary tract [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Metastases to bone [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Metastases to liver [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Metastases to penis [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Neoplasm malignant [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Non-hodgkin's lymphoma unspecified histology indolent [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Pleural mesothelioma malignant [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Prostate cancer [A] †	3/207 (1.45%)	4/202 (1.98%)	1/69 (1.45%)	2/66 (3.03%)
Prostate cancer metastatic [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Squamus cell carcinoma [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Squamus cell carcinoma of skin [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Nervous system disorders				
Cerebral haemorrhage [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cerebral infarction [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cerebral ischaemia [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cerebrovascular accident [A] †	0/207 (0%)	2/202 (0.99%)	2/69 (2.9%)	1/66 (1.52%)
Cerebrovascular insufficiency [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Haemorrhagic stroke [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Hemiparesis [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Hyperkinesia [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Parkinson's disease [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Spinal cord compression [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Syncope [A] †	1/207 (0.48%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Transient ischaemic attack [A] †	0/207 (0%)	1/202 (0.5%)	1/69 (1.45%)	0/66 (0%)
Psychiatric disorders				
Confusional state [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Renal and urinary disorders				
Bladder obstruction [A] †	0/207 (0%)	2/202 (0.99%)	0/69 (0%)	0/66 (0%)
Calculus bladder [A] †	2/207 (0.97%)	1/202 (0.5%)	0/69 (0%)	1/66 (1.52%)
Calculus ureteric [A] †	2/207 (0.97%)	0/202 (0%)	0/69 (0%)	2/66 (3.03%)
Haematuria [A] †	1/207 (0.48%)	3/202 (1.49%)	0/69 (0%)	0/66 (0%)
Hydronephrosis [A] †	0/207 (0%)	2/202 (0.99%)	0/69 (0%)	0/66 (0%)
Renal failure [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Renal failure acute [A] †	1/207 (0.48%)	2/202 (0.99%)	1/69 (1.45%)	0/66 (0%)
Renal failure chronic [A] †	0/207 (0%)	2/202 (0.99%)	0/69 (0%)	1/66 (1.52%)
Ureteric stenosis [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Urethral obstruction [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Urethral stenosis [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Urinary incontinence [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Urinary retention [A] †	1/207 (0.48%)	6/202 (2.97%)	2/69 (2.9%)	2/66 (3.03%)
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Cough [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Dyspnoea [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Pleural effusion [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Respiratory failure [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Skin and subcutaneous tissue disorders				
Ecchymosis [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Surgical and medical procedures				
Transurethral prostatectomy [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Vascular disorders				
Aortic aneurysm [A] †	0/207 (0%)	0/202 (0%)	0/69 (0%)	1/66 (1.52%)
Deep vein thrombosis [A] †	0/207 (0%)	0/202 (0%)	2/69 (2.9%)	0/66 (0%)
Hypertension [A] †	1/207 (0.48%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Hypotension [A] †	1/207 (0.48%)	0/202 (0%)	0/69 (0%)	0/66 (0%)
Lymphoedema [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)
Orthostatic hypotension [A] †	0/207 (0%)	1/202 (0.5%)	1/69 (1.45%)	0/66 (0%)
Pallor [A] †	0/207 (0%)	1/202 (0.5%)	0/69 (0%)	0/66 (0%)
Varicose vein [A] †	0/207 (0%)	0/202 (0%)	1/69 (1.45%)	0/66 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

Other Adverse Events

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

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	181/207 (87.44%)	177/202 (87.62%)	63/69 (91.3%)	58/66 (87.88%)
Blood and lymphatic system disorders				
Anaemia [A] †	17/207 (8.21%)	18/202 (8.91%)	10/69 (14.49%)	6/66 (9.09%)
Cardiac disorders				
Atrial fibrillation [A] †	2/207 (0.97%)	6/202 (2.97%)	4/69 (5.8%)	4/66 (6.06%)
Myocardial infarction [A] †	4/207 (1.93%)	2/202 (0.99%)	1/69 (1.45%)	4/66 (6.06%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Ear and labyrinth disorders				
Vertigo [A] †	2/207 (0.97%)	4/202 (1.98%)	1/69 (1.45%)	6/66 (9.09%)
Gastrointestinal disorders				
Constipation [A] †	18/207 (8.7%)	12/202 (5.94%)	9/69 (13.04%)	2/66 (3.03%)
Diarrhoea [A] †	17/207 (8.21%)	13/202 (6.44%)	12/69 (17.39%)	10/66 (15.15%)
Dyspepsia [A] †	3/207 (1.45%)	8/202 (3.96%)	1/69 (1.45%)	3/66 (4.55%)
Haemorrhoids [A] †	1/207 (0.48%)	5/202 (2.48%)	4/69 (5.8%)	0/66 (0%)
Nausea [A] †	10/207 (4.83%)	15/202 (7.43%)	3/69 (4.35%)	6/66 (9.09%)
Vomiting [A] †	4/207 (1.93%)	7/202 (3.47%)	6/69 (8.7%)	3/66 (4.55%)
General disorders				
Asthenia [A] †	13/207 (6.28%)	13/202 (6.44%)	8/69 (11.59%)	3/66 (4.55%)
Chest pain [A] †	2/207 (0.97%)	3/202 (1.49%)	4/69 (5.8%)	0/66 (0%)
Chills [A] †	16/207 (7.73%)	11/202 (5.45%)	3/69 (4.35%)	2/66 (3.03%)
Fatigue [A] †	12/207 (5.8%)	15/202 (7.43%)	9/69 (13.04%)	6/66 (9.09%)
Injection site erythema [A] †	40/207 (19.32%)	51/202 (25.25%)	10/69 (14.49%)	16/66 (24.24%)
Injection site induration [A] †	9/207 (4.35%)	13/202 (6.44%)	1/69 (1.45%)	3/66 (4.55%)
Injection site inflammation [A] †	7/207 (3.38%)	5/202 (2.48%)	6/69 (8.7%)	0/66 (0%)
Injection site nodule [A] †	13/207 (6.28%)	17/202 (8.42%)	4/69 (5.8%)	2/66 (3.03%)
Injection site pain [A] †	65/207 (31.4%)	67/202 (33.17%)	20/69 (28.99%)	16/66 (24.24%)
Injection site swelling [A] †	17/207 (8.21%)	16/202 (7.92%)	6/69 (8.7%)	4/66 (6.06%)
Oedema peripheral [A] †	8/207 (3.86%)	9/202 (4.46%)	4/69 (5.8%)	3/66 (4.55%)
Pyrexia [A] †	20/207 (9.66%)	22/202 (10.89%)	8/69 (11.59%)	9/66 (13.64%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Infections and infestations				
Bronchitis [A] †	8/207 (3.86%)	6/202 (2.97%)	4/69 (5.8%)	4/66 (6.06%)
Influenza [A] †	12/207 (5.8%)	10/202 (4.95%)	8/69 (11.59%)	2/66 (3.03%)
Nasopharyngitis [A] †	11/207 (5.31%)	7/202 (3.47%)	5/69 (7.25%)	5/66 (7.58%)
Upper respiratory tract infection [A] †	4/207 (1.93%)	10/202 (4.95%)	5/69 (7.25%)	3/66 (4.55%)
Urinary tract infection [A] †	12/207 (5.8%)	10/202 (4.95%)	14/69 (20.29%)	10/66 (15.15%)
Injury, poisoning and procedural complications				
Fall [A] †	6/207 (2.9%)	8/202 (3.96%)	4/69 (5.8%)	0/66 (0%)
Investigations				
Alanine aminotransferase increased [A] †	19/207 (9.18%)	21/202 (10.4%)	6/69 (8.7%)	6/66 (9.09%)
Aspartate aminotransferase increased [A] †	15/207 (7.25%)	14/202 (6.93%)	7/69 (10.14%)	5/66 (7.58%)
Blood alkaline phosphatase increased [A] †	7/207 (3.38%)	11/202 (5.45%)	3/69 (4.35%)	2/66 (3.03%)
Blood creatinine increased [A] †	11/207 (5.31%)	9/202 (4.46%)	5/69 (7.25%)	4/66 (6.06%)
Blood urea increased [A] †	9/207 (4.35%)	5/202 (2.48%)	4/69 (5.8%)	0/66 (0%)
Gamma-glutamyltransferase increased [A] †	8/207 (3.86%)	15/202 (7.43%)	7/69 (10.14%)	2/66 (3.03%)
Prostatic specific antigen increased [A] †	16/207 (7.73%)	20/202 (9.9%)	10/69 (14.49%)	6/66 (9.09%)
Weight decreased [A] †	20/207 (9.66%)	24/202 (11.88%)	19/69 (27.54%)	10/66 (15.15%)
Weight increased [A] †	32/207 (15.46%)	25/202 (12.38%)	15/69 (21.74%)	14/66 (21.21%)
Metabolism and nutrition disorders				
Decreased appetite [A] †	3/207 (1.45%)	4/202 (1.98%)	7/69 (10.14%)	1/66 (1.52%)
Hypercholesterolaemia [A] †	13/207 (6.28%)	18/202 (8.91%)	3/69 (4.35%)	5/66 (7.58%)
Musculoskeletal and connective tissue disorders				

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Arthralgia [A] †	18/207 (8.7%)	14/202 (6.93%)	14/69 (20.29%)	7/66 (10.61%)
Back pain [A] †	20/207 (9.66%)	20/202 (9.9%)	10/69 (14.49%)	8/66 (12.12%)
Muscle spasms [A] †	1/207 (0.48%)	5/202 (2.48%)	4/69 (5.8%)	2/66 (3.03%)
Myalgia [A] †	3/207 (1.45%)	4/202 (1.98%)	2/69 (2.9%)	3/66 (4.55%)
Osteoarthritis [A] †	8/207 (3.86%)	45/202 (22.28%)	4/69 (5.8%)	2/66 (3.03%)
Osteoporosis [A] †	0/207 (0%)	5/202 (2.48%)	1/69 (1.45%)	3/66 (4.55%)
Pain in extremity [A] †	6/207 (2.9%)	9/202 (4.46%)	7/69 (10.14%)	3/66 (4.55%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Basal cell carcinoma [A] †	3/207 (1.45%)	5/202 (2.48%)	1/69 (1.45%)	3/66 (4.55%)
Metastases to bone [A] †	6/207 (2.9%)	7/202 (3.47%)	2/69 (2.9%)	4/66 (6.06%)
Prostate cancer [A] †	12/207 (5.8%)	11/202 (5.45%)	5/69 (7.25%)	6/66 (9.09%)
Nervous system disorders				
Dizziness [A] †	13/207 (6.28%)	14/202 (6.93%)	5/69 (7.25%)	6/66 (9.09%)
Headache [A] †	11/207 (5.31%)	10/202 (4.95%)	5/69 (7.25%)	5/66 (7.58%)
Psychiatric disorders				
Depression [A] †	3/207 (1.45%)	11/202 (5.45%)	4/69 (5.8%)	6/66 (9.09%)
Insomnia [A] †	10/207 (4.83%)	9/202 (4.46%)	2/69 (2.9%)	8/66 (12.12%)
Renal and urinary disorders				
Calculus ureteric [A] †	2/207 (0.97%)	0/202 (0%)	0/69 (0%)	3/66 (4.55%)
Cystitis noninfective [A] †	2/207 (0.97%)	2/202 (0.99%)	0/69 (0%)	3/66 (4.55%)
Dysuria [A] †	5/207 (2.42%)	11/202 (5.45%)	6/69 (8.7%)	4/66 (6.06%)
Haematuria [A] †	10/207 (4.83%)	11/202 (5.45%)	4/69 (5.8%)	3/66 (4.55%)

	Degarelix 80 mg / Degarelix 80 mg	Degarelix 160 mg / Degarelix 160 mg	Leuprolide 7.5 mg / Degarelix 80 mg	Leuprolide 7.5 mg / Degarelix 160 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hydronephrosis [A] †	3/207 (1.45%)	5/202 (2.48%)	2/69 (2.9%)	4/66 (6.06%)
Nocturia [A] †	6/207 (2.9%)	4/202 (1.98%)	2/69 (2.9%)	3/66 (4.55%)
Urinary retention [A] †	5/207 (2.42%)	14/202 (6.93%)	7/69 (10.14%)	6/66 (9.09%)
Reproductive system and breast disorders				
Erectile dysfunction [A] †	4/207 (1.93%)	4/202 (1.98%)	3/69 (4.35%)	5/66 (7.58%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	14/207 (6.76%)	8/202 (3.96%)	5/69 (7.25%)	2/66 (3.03%)
Dyspnoea [A] †	6/207 (2.9%)	4/202 (1.98%)	1/69 (1.45%)	3/66 (4.55%)
Vascular disorders				
Hot flush [A] †	62/207 (29.95%)	63/202 (31.19%)	20/69 (28.99%)	21/66 (31.82%)
Hypertension [A] †	19/207 (9.18%)	27/202 (13.37%)	8/69 (11.59%)	5/66 (7.58%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

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. Additional time may be required to allow Ferring to seek patent protection of the invention.

Results Point of Contact:

Name/Official Title: Clinical Development Support

Organization: Ferring Pharmaceuticals

Phone:

Email: DK0-Disclosure@ferring.com