ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 03/15/2012

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Study Identification

Unique Protocol ID:	ARI109924
Brief Title:	ARTS - AVODART After Radical Therapy For Prostate Cancer Study
Official Title:	A Randomised, Double-Blind, Placebo-Controlled Trial Assessing the Efficacy and Safety of Dutasteride (AVODART™) 0.5 mg in Extending the Time to PSA Doubling in Men With Prostate Cancer and Biochemical Failure (PSA Increase) After Radical Therapy With Curative Intent
Secondary IDs:	

Study Status

Record Verification:	December 2011
Overall Status:	Completed
Study Start:	November 2007
Primary Completion:	December 2010 [Actual]
Study Completion:	March 2011 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 12-09-2007 Board Name: CEIC Hospital Universitario de Getafe Board Affiliation: no affiliation Phone: +34 91 6839360 Email: cei.hugf@salud.madrid.org
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Spain: Ministry of Health

Study Description

Brief Summary:	ARI109924 will be a 2-year, multicentre, randomised, double-blind, placebo-controlled trial assessing the efficacy and safety of dutasteride in extending time to prostate specific antigen (PSA) doubling in men who have been treated for clinically localised prostate cancer (PCa) with a radical therapy (radical prostatectomy, primary radiotherapy or salvage radiotherapy) with curative intent but who experience a biochemical failure (PSA rise) afterwards without signs or symptoms of metastases.
Detailed Description:	A Randomised, Double-Blind, Placebo-Controlled Trial Assessing the Efficacy and Safety of Dutasteride (AVODART™) 0.5 mg in Extending the Time to PSA Doubling in Men with Prostate Cancer and Biochemical Failure (PSA increase) after Radical Therapy with Curative Intent (ARTS - AVODART after Radical Therapy for prostate cancer Study)

Conditions

Conditions:	Neoplasms, Prostate Prostate Cancer After a Radical Treatment
Keywords:	Prostate Cancer AVODART PSA dutasteride dutasteride PSADT PSA Prostate specific antigen Prostate Cancer AVODART radical therapy radical therapy

doubling time
PSADT
Prostate specific antigen
doubling time

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	294 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Avodart Patients will receive a 3-month supply of study drug or placebo. Patients will be instructed to take one capsule by mouth once daily. Study medication will be supplied at 3-month intervals during scheduled clinic visits for a total of 24 months.	Drug: Avodart 0.5 mg administered orally once daily Other Names: • Avodart/placebo Drug: Avodart 0.5 mg administered orally once daily Other Names: • Avodart/placebo
Placebo Comparator: Placebo Arm Patients will receive a 3-month supply of study drug or placebo. Patients will be instructed to take one capsule by mouth once daily. Study medication will be supplied at 3-month intervals during scheduled clinic visits for a total of 24 months.	placebo Patients will be randomized at Visit 2 in 1:1 ratio to receive either 0.5 mg dutasteride or placebo placebo Patients will be randomized at Visit 2 in 1:1 ratio to receive either 0.5 mg dutasteride or placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 85 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

Patients eligible for enrolment in the study must meet all of the following criteria:

- Males <85 years of age
- No clinically relevant abnormal findings on the screening ECG
- Patients with asymptomatic PSA failure following radical therapy with curative intent for clinically localised prostate cancer. PSA failure is defined as:
- After primary radiotherapy:
- 3 rises in PSA levels from nadir PSA, with each determination at least 4 weeks apart and a final PSA level ≥2 ng/mL above nadir PSA
- Time from radiotherapy should be at least 1 year from termination of radiotherapy treatment
- After radical prostatectomy with or without salvage radiotherapy:
- 3 rises in PSA level from nadir PSA, with each determination at least 4 weeks apart and each PSA level ≥0.2 ng/mL and a final PSA level ≥0.4 ng/mL (nadir PSA is defined as the lowest PSA value achieved after therapy)
- Serum PSA levels:
- ≥2 ng/mL and ≤20ng/mL for primary radiotherapy patients
- ≥0.4 ng/ml and ≤10ng/ml for radical prostatectomy with or without salvage radiotherapy patients
- PSADT >3 months and ≤24 months
- Clinical stage T1-T3a N0 M0
- Non-metastatic prostate cancer, as confirmed on a negative bone scan performed within 6 months prior to randomisation (Visit 2)3.
- No evidence of local recurrence in radical prostatectomy or salvage radiotherapy patients
- Expected survival ≥2 years
- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2 (see Appendix 1)

Miscellaneous:

- Able to swallow and retain oral medication
- Able and willing to participate in the full 2 years of the study
- Able to read and write (the MAX-PC questionnaire is self-administered), understand instructions related to study procedures and give written informed consent

- In France, a patient will be eligible for inclusion in this study only if either affiliated to or a beneficiary of a social security category.

Exclusion Criteria:

- Any unstable serious co-existing medical condition(s) including but not limited to myocardial infarction, coronary bypass surgery, unstable angina, cardiac arrhythmias, clinically evident congestive heart failure or cerebrovascular accident within 6 months prior to Visit 1, or uncontrolled diabetes or peptic ulcer disease which is uncontrolled by medical management
- Abnormal liver function tests (greater than 2 times the upper limit of normal [ULN] for alanine aminotransferase [ALT], aspartate aminotransferase [AST] or alkaline phosphatase [ALP] or >1.5 x ULN for bilirubin).
- Serum creatinine >1.5 x ULN
- History of another malignancy within 5 years that could affect the diagnosis of prostate cancer
- History or current evidence of drug or alcohol abuse within 12 months prior to Visit 1
- History of any illness (including psychiatric) that, in the opinion of the investigator, might confound the results of the study or pose additional risk to the patient
- Known hypersensitivity to any 5-AR inhibitor or to any drug chemically related to dutasteride

Disease characteristics:

- Serum PSA levels
- >20 ng/mL in primary radiotherapy patients
- >10 ng/mL in radical prostatectomy with or without salvage radiotherapy patients
- PSADT ≤3 months or >24 months
- Biochemical failures in post brachytherapy patients
- Clinical stage N+ or M+
- Patient has previously been treated for prostate cancer with any of the following:
- Chemotherapy
- Oestrogens (e.g. megestrol, medroxyprogesterone, cyproterone, Diethylstilbestrol [DES])
- Drugs with anti-androgenic properties (e.g. spironolactone if >50mg/day, flutamide, bicalutamide, ketoconazole, progestational agents), (except when used for adjuvancy or neoadjuvancy in the context of a primary radical treatment in which case their use should have been for no more than 6 months and should have completed at least 1 year before Visit 1 [Note: the use of topical ketoconazole is permitted prior to and during the study and the use of cimetidine is permitted prior to study entry]
- GnRH analogues (e.g., leuprolide, goserelin) except when used for adjuvancy or neoadjuvancy in the context of a primary radical treatment (in this case use should have been for no more than 6 months and should have finalised at least 1 year before Visit 1)
- Orchiectomy

Concomitant medications:

- Glucocorticoids, except inhaled or topical, are not permitted within 3 months prior to Visit 1 or during the study
- Current and/or previous use of finasteride (Proscar, Propecia) or dutasteride (GI198745, AVODART™) exposure within 6 months prior to Visit 1
- Anabolic steroids within 6 months prior to Visit 1
- Participation in any other investigational or marketed drug trial within the 30 days prior to Visit 1 or any time during the study period

Contacts/Locations

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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Overall Study

	Placebo	Dutasteride 0.5 mg
Started	147	147
Completed	76	111
Not Completed	71	36
Physician Decision	18	4
Withdrawal by Subject	11	4
Adverse Event	5	5
Lack of Efficacy	2	2
Protocol Violation	2	1
Lost to Follow-up	0	1
Met Protocol-defined Stopping Criteria	32	16
Randomized in Error	1	2
Hospitalized; Unable to Continue	0	1

Baseline Characteristics

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Baseline Measures

	Placebo	Dutasteride 0.5 mg	Total
Number of Participants	147	147	294
Age, Continuous [units: Years] Mean (Standard Deviation)	68.6 (6.53)	69.7 (5.76)	69.1 (6.17)
Gender, Male/Female [units: Participants]			
Female	0	0	0
Male	147	147	294
Race/Ethnicity, Customized [units: participants]			
White - Caucasian/European Heritage	145	147	292
White - Arabic/North African Heritage	1	0	1
Asian - Central/Soth Asian Heritage	1	0	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Time to Prostate-specific Antigen (PSA) Doubling From Baseline (in Days)
Measure Description	Time to PSA doubling is defined as the number of days between the baseline date and the study day of the first post-baseline PSA evaluation date (within treatment period, typically up to 24-month evaluations) on which the PSA value was at least twice as much as the baseline PSA value, and the immediate subsequent value, if available, was at least 85% of two times the baseline value. Participants who never achieved PSA doubling were censored at the last post-baseline, non-missing PSA evaluation.
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population: all participants randomized to study treatment. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm; 1 in dutasteride arm). Only participants who experienced PSA doubling (82 in placebo, 41 in dutasteride) contributed to summary statistics.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Time to Prostate-specific Antigen (PSA) Doubling From Baseline (in Days) [units: days] Median (Full Range)		
Participants (par.) with PSA doubling; n=82, 41	365.5 (90 to 736)	458.0 (91 to 736)
Par. without PSA doubling (censored); n=62, 105	NA (NA to NA) [1]	NA (NA to NA) [1]

[1] Data were not summarized for participants with censored time.

Statistical Analysis 1 for Time to Prostate-specific Antigen (PSA) Doubling From Baseline (in Days)

Statistical Analysis Overview	Comparison Groups	Placebo, Dutasteride 0.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Comparing 24-month survival curves (includes time to PSA doubling as well as time to censoring); stratified by site cluster and previous therapy
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Relative Risk (Hazard Ratio)]
	Estimated Value	0.34
	Confidence Interval	(2-Sided) 95% 0.23 to 0.50

	Estimation Comments	Relative risk of dutasteride compared to placebo, derived from Cox Proportional Hazard model stratified by site cluster and previous therapy

2. Primary Outcome Measure:

Measure Title	Number of Participants With PSA Doubling From Baseline
Measure Description	PSA doubling is defined as the first post-baseline PSA value (within treatment period, typically up to 24-month evaluations) that was at least twice as much as the baseline PSA value and was confirmed as such (at least 85% of two times the baseline PSA value) in the immediate subsequent PSA value if one is available.
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Number of Participants With PSA Doubling From Baseline [units: participants]		
With PSA doubling	82	41
Without PSA doubling	62	105

Statistical Analysis 1 for Number of Participants With PSA Doubling From Baseline

Statistical Analysis Overview	Comparison Groups	Placebo, Dutasteride 0.5 mg
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Comparing percentages of participants with PSA doubling: 57% versus 28%
	Method	Other [Mantel-Haenszel Chi-Square]
	Comments	[Not specified]

3. Primary Outcome Measure:

Measure Title	Time to PSA Doubling From Baseline (in Days) Within Year 1
Measure Description	Time to PSA doubling is defined as the number of days between the baseline date and the study day of the first post-baseline PSA evaluation date within Year 1 (Y1; within treatment period, typically up to 12-month evaluations) on which the PSA value was at least twice as much as the baseline PSA value, and the immediate subsequent value, if available, was at least 85% of two times the baseline value.
Time Frame	up to 16 months
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm). Only participants with PSA doubling within Year 1 (50 in placebo, 15 in dutasteride) contributed to summary statistics.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Time to PSA Doubling From Baseline (in Days) Within Year 1 [units: days] Median (Full Range)		
Participants with PSA doubling in Y1; n=50, 15	273.5 (90 to 486)	183.0 (91 to 383)

	Placebo	Dutasteride 0.5 mg
Participants without PSA doubling in Y1: n=94, 131	NA (NA to NA) [1]	NA (NA to NA) [1]

[1] Data were not summarized for participants with censored time.

Statistical Analysis 1 for Time to PSA Doubling From Baseline (in Days) Within Year 1

Statistical Analysis Overview	Comparison Groups	Placebo, Dutasteride 0.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Comparing 12-month survival curves (includes time to PSA doubling as well as time to censoring); stratified by site cluster and previous therapy
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Relative Risk (Hazard Ratio)]
	Estimated Value	0.25
	Confidence Interval	(2-Sided) 95% 0.14 to 0.45
	Estimation Comments	Relative risk of dutasteride compared to placebo, derived from Cox proportional hazard model stratified by site cluster and previous therapy

4. Primary Outcome Measure:

Measure Title	Number of Participants With PSA Doubling From Baseline During Year 1
Measure Description	PSA doubling is defined as the first post-baseline PSA value (within treatment period, typically up to 12-month evaluations) that was at least twice as much as the baseline PSA value and was confirmed as such (at least 85% of two times the baseline PSA value) in the immediate subsequent PSA value if one is available.
Time Frame	up to 16 months
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Number of Participants With PSA Doubling From Baseline During Year 1 [units: participants]		
With PSA doubling	50	15
Without PSA doubling	94	131

Statistical Analysis 1 for Number of Participants With PSA Doubling From Baseline During Year 1

Statistical Analysis Overview	Comparison Groups	Placebo, Dutasteride 0.5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Comparing percentages of participants with PSA doubling: 35% versus 10%
	Method	Other [Mantel-Haenszel Chi-Square]
	Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Time to Disease Progression From Baseline (in Days)

Measure Description	Time to disease progression is defined as the number of days between baseline and the first occurrence of any of the following: PSA doubling time (PSADT)<=91 days, PSA value is at least 50% more than baseline value (>20 nanogram/milliliter [ng/ml] for primary radiotherapy group or >10 ng/ml for radical prostatectomy group), rescue treatment, cancer-positive biopsy, cancer-positive bone scan. (Confirmation of PSA criteria is required in an immediate subsequent PSA, if available, and PSA values for consideration are restricted to treatment period, typically up to 24-month evaluations.)
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants with disease progression have been summarized.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	49	25
Time to Disease Progression From Baseline (in Days) [units: days] Median (Full Range)	365.0 (39 to 824)	285.0 (22 to 808)

6. Secondary Outcome Measure:

Measure Title	Number of Participants With Disease Progression
Measure Description	Disease progression is defined as the first occurrence of any of the following: PSADT<=91 days, PSA value is at least 50% more than baseline value (>20 ng/ml for primary radiotherapy group or >10 ng/ml for radical prostatectomy group), rescue treatment, cancer-positive biopsy, cancer-positive bone scan. If one of the PSA criteria is qualifying (within treatment period, typically up to 24-month evaluations), an immediate subsequent PSA, if available, must confirm either criterion (or at least 85% of the qualifying value).
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Number of Participants With Disease Progression [units: participants]		
With disease progression	49	25
Without disease progression	95	121

7. Secondary Outcome Measure:

Measure Title	Number of Participants Classified as Treatment Responders at Months 3, 6, 9, 12, 15, 18, 21, and 24
Measure Description	Treatment responders at Month X were defined as participants (par.) with either a PSA decrease or an increase <=15% from baseline to Month X confirmed in all PSA measurements between baseline (BL) and Month X.
Time Frame	Months 3, 6, 9, 12, 15, 18, 21, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Par. not having a post-BL measurement could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm). Different par. may contribute data at different time points (TP); the number of par. analyzed at each TP are those with BL as well as post-baseline data at the particular TP.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Number of Participants Classified as Treatment Responders at Months 3, 6, 9, 12, 15, 18, 21, and 24 [units: participants]		
Month 3, n=141, 141	64	117
Month 6, n=131, 135	36	105
Month 9, n=121, 129	22	95
Month 12, n=110, 124	13	87
Month 15, n=100, 121	10	82
Month 18, n=95, 120	8	76
Month 21, n=83, 112	7	70
Month 24, n=76, 110	6	62

8. Secondary Outcome Measure:

Measure Title	Time to PSA Rise From Baseline (in Days)
Measure Description	A participant was designated as having a PSA rise if there existed a post-baseline PSA value (within treatment period, typically up to 24-month evaluations) that was >1.15 times the baseline PSA value, and all subsequent PSA values were >1.15 times the baseline PSA value. The study day for the first PSA evaluation that qualified for analysis of PSA rise was used for time to PSA rise. If none of the post-baseline PSA values qualified for analysis of PSA rise during the study, time to PSA rise was censored at the last post-baseline PSA evaluation.
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants with PSA rise have been summarized.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	127	72
Time to PSA Rise From Baseline (in Days) [units: days] Median (Full Range)	100.0 (39 to 729)	279.0 (22 to 805)

9. Secondary Outcome Measure:

Measure Title	Number of Participants With a PSA Rise From Baseline
Measure Description	A participant was designated as having a PSA rise if there existed a post-baseline PSA value (within treatment period, typically up to 24-month evluations) that was >1.15 times the baseline PSA value, and all subsequent PSA values were >1.15 times the baseline PSA value.
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Number of Participants With a PSA Rise From Baseline [units: participants]		
With PSA rise	127	72
Without PSA rise	17	74

10. Secondary Outcome Measure:

Measure Title	Time to PSA Progression (in Days)
Measure Description	A participant was designated as having PSA progression if there existed a post-baseline PSA value (within treatment period, typically up to 24-month evaluations) that was >10 ng/ml if radical prostatectomy or >20 ng/ml if primary radiotherapy and PSA >=1.5 times the baseline PSA value, or 0<PSADT<=91 days, and all subsequent PSA values satisfied these criteria. The study day for the first PSA qualifying for progression was used for time to PSA progression. If none of the PSA values qualified for PSA progression, time to PSA progression was censored at the last post-baseline PSA evaluation.
Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants with PSA progression have been summarized.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	25	19
Time to PSA Progression (in Days) [units: days] Median (Full Range)	368.0 (90 to 736)	368.0 (22 to 735)

11. Secondary Outcome Measure:

Measure Title	Number of Participants With PSA Progression
Measure Description	A participant was designated as having a PSA progression if there existed a post-baseline PSA value (within treatment period, typically up to 24-month evaluations) that was (>10 ng/ml if radical prostatectomy or >20 ng/ml if primary radiotherapy) and PSA >=1.5 times the baseline PSA value), or 0<PSADT<=91 days, and all subsequent PSA values satisfied either of these criteria.

Time Frame	up to 28 months
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Number of Participants With PSA Progression [units: participants]		
With PSA progression	25	19
Without PSA progression	119	127

12. Secondary Outcome Measure:

Measure Title	Change in Total PSA From Baseline at Months 12 and 24
Measure Description	Change in PSA from baseline at Month X = Month X PSA - Baseline PSA. The missing PSA value for scheduled visits could have been replaced by non-missing PSA values within 30 days after the clinic visit date. If such replacement was not possible, the latest non-missing post-baseline PSA before the scheduled visit was used for the scheduled visit PSA (Last Observation Carried Forward).
Time Frame	Baseline; Months 12 and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Change in Total PSA From Baseline at Months 12 and 24 [units: nanograms/milliliter (ng/ml)] Mean (Standard Deviation)		
Month 12	2.3 (4.86)	0.9 (7.25)
Month 24	3.9 (6.09)	2.3 (7.60)

13. Secondary Outcome Measure:

Measure Title	Percent Change in Total PSA From Baseline at Months 12 and 24
Measure Description	Percent change in PSA from baseline at Month X = 100*(Month X PSA - Baseline PSA)/Baseline PSA. The missing PSA value for scheduled visits could have been replaced by non-missing PSA values within 30 days after the clinic visit date. If such replacement was not possible, the latest non-missing post-baseline PSA before the scheduled visit was used for the scheduled visit PSA (Last Observation Carried Forward).
Time Frame	Baseline; Months 12 and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Percent Change in Total PSA From Baseline at Months 12 and 24 [units: percent change] Mean (Standard Deviation)		
Month 12	93.1 (115.02)	11.8 (103.41)
Month 24	197.3 (282.41)	86.2 (193.95)

14. Secondary Outcome Measure:

Measure Title	Change in PSA From Nadir PSA at Months 12 and 24
Measure Description	Change from nadir PSA at Month X = Month X PSA – nadir PSA. Nadir PSA was reported by the site as the lowest historical PSA value after the radical therapy. A nadir value below the detection level was captured as 0.0. The missing PSA value for scheduled visits could have been replaced by non-missing PSA values within 30 days after the clinic visit date. If such replacement was not possible, the latest non-missing post-baseline PSA before the scheduled visit was used for the scheduled visit PSA (Last Observation Carried Forward).
Time Frame	Baseline; Months 12 and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	146
Change in PSA From Nadir PSA at Months 12 and 24 [units: ng/ml]		

	Placebo	Dutasteride 0.5 mg
Mean (Standard Deviation)		
Month 12	4.7 (6.31)	3.5 (9.04)
Month 24	6.3 (7.34)	4.9 (9.65)

15. Secondary Outcome Measure:

Measure Title	Percent Change in PSA From Nadir PSA at Months 12 and 24
Measure Description	Percent change from nadir PSA at Month X = 100*(Month X PSA – nadir PSA)/Nadir PSA. Nadir PSA was reported by the site as the lowest historical PSA value after the radical therapy. A nadir value below the detection level was captured as 0.0. The missing PSA value for scheduled visits could have been replaced by non-missing PSA values within 30 days after the clinic visit date. If such replacement was not possible, the latest non-missing post-baseline PSA before the scheduled visit was used for the scheduled visit PSA (Last Observation Carried Forward).
Time Frame	Baseline; Months 12 and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having any post-baseline PSA measurements could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 1 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	94	98
Percent Change in PSA From Nadir PSA at Months 12 and 24 [units: percent change] Mean (Standard Deviation)		
Month 12	2810.3 (4062.48)	2120.7 (5284.72)
Month 24	4036.1 (5860.98)	2927.2 (6146.34)

16. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change in PSA Doubling Time (PSADT) From Baseline at Month 12, Month 24, and End-of-treatment (up to 28 Months)
Measure Description	Participants with improvement included those whose PSADT at a specified visit was positive but more than the baseline PSADT, whose PSA at the visit was the same as the baseline PSA, or whose PSA at the visit was less than the baseline PSA. Participants with worsening included those whose PSADT at the visit was positive but less than the baseline PSADT.
Time Frame	Baseline; Month 12, Month 24, End-of-Treatment (up to 28 months)
Safety Issue?	No

Analysis Population Description

ITT Population. Participants having no baseline (BL) PSADT (due to incomplete PSA data or no rise in PSA at BL) or no post-BL measurement could not be evaluated and were hence excluded from this analysis (3 in placebo arm, 3 in dutasteride arm). Participants with missing PSA data at a specific visit were excluded from that visit's analysis .

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	144
Number of Participants With the Indicated Change in PSA Doubling Time (PSADT) From Baseline at Month 12, Month 24, and End-of-treatment (up to 28 Months) [units: participants]		
Month 12, Worsening; n=110, 123	20	7
Month 12, No change; n=110, 123	0	0
Month 12, Improvement; n=110, 123	90	116
Month 24, Worsening; n=76, 110	7	3
Month 24, No change; n=76, 110	0	0
Month 24, Improvement; n=76, 110	69	107

	Placebo	Dutasteride 0.5 mg
End-of treatment, Worsening; n=144, 144	37	19
End-of treatment, No change; n=144, 144	0	0
End-of treatment, Improvement; n=144, 144	107	125

17. Secondary Outcome Measure:

Measure Title	Changes From Baseline in Disease-related Anxiety Measured by the Memorial Anxiety Scale for Prostate Cancer (MAX-PC)
Measure Description	MAX-PC is an 18-item, self-reported measure that evaluates prostate cancer-related anxiety. The score ranges from 0 to 54, and an increase in the score indicates a worsened anxiety level. Change from Baseline at Month X = Month X MAX-PC score - Baseline MAX-PC score. A missing post-baseline value is replaced by the last available post-baseline value (Last Observation Carried Forward(LOCF)). A general linear model controls for previous therapy, site cluster, and baseline MAX-PC score.
Time Frame	Baseline; Months 3, 6, 12, 18, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Participants not having a baseline value or not having any post-baseline value could not be evaluated for this endpoint and were hence excluded from this analysis (3 in placebo arm, 4 in dutasteride arm). Participants were excluded from a specific visit analysis if the value for the visit (after LOCF application) was missing.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	144	143
Changes From Baseline in Disease-related Anxiety Measured by the Memorial Anxiety Scale for Prostate Cancer (MAX-PC) [units: scores on a scale] Least Squares Mean (Standard Error)		

	Placebo	Dutasteride 0.5 mg
Month 3, n=144, 141	-1.6 (0.63)	-1.4 (0.63)
Month 6, n=144, 143	-2.2 (0.63)	-3.1 (0.62)
Month 12, n=144, 143	-0.8 (0.72)	-2.9 (0.72)
Month 18, n=144, 143	-1.1 (0.79)	-2.2 (0.78)
Month 24, n=144, 143	-0.4 (0.78)	-1.4 (0.77)

18. Secondary Outcome Measure:

Measure Title	Number of Participants With a Shift From Normal at Baseline to at Least One Abnormal Laboratory Value for Any Parameter Any Time During the Study
Measure Description	A participant has a normal value for a laboratory parameter if the value is within the low and high range of normal provided by the laboratory. Each laboratory parameter is evaluated for shift from normal at baseline to abnormal any time post-baseline. A participant with any laboratory parameter showing this shift is counted. A participant is counted only once even if he had such a shift in more than one laboratory parameter or more than once among all post-baseline evaluations.
Time Frame	Baseline; up to 28 months
Safety Issue?	Yes

Analysis Population Description

ITT Population. Participants not having any baseline measurements, or having a baseline but no post-baseline measurements of at least one of the same parameter could not be evaluated and were hence excluded from this analysis (7 in placebo arm, 9 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	140	138
Number of Participants With a Shift From Normal at Baseline to at Least One Abnormal Laboratory Value for Any Parameter Any Time During the Study	74	64

	Placebo	Dutasteride 0.5 mg
[units: participants]		

19. Secondary Outcome Measure:

Measure Title	Number of Participants With a Threshold Laboratory Value for Any Parameter at Baseline (BL) and Any Time Post-baseline
Measure Description	Threshold laboratory values are defined in terms of a multiplicative factor of the testing laboratory's normal range, pre-specified in the analysis plan. A laboratory value that is above the upper limit factor multiplied by the upper limit of the normal range is considered a high threshold value. A laboratory value that is below the lower limit factor multiplied by the lower limit of the normal range is considered a low threshold value.
Time Frame	Baseline; up to 28 months
Safety Issue?	Yes

Analysis Population Description

ITT Population. Participants not having a baseline as well as a post-baseline measurement of at least one laboratory parameter could not be evaluated and were hence excluded from this analysis (7 in placebo arm, 9 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	140	138
Number of Participants With a Threshold Laboratory Value for Any Parameter at Baseline (BL) and Any Time Post-baseline [units: participants]		
Threshold at BL	5	9
Non-threshold at BL; threshold at any time post-BL	11	5

20. Secondary Outcome Measure:

Measure Title	Number of Participants With Palpable Breast Tissue (PBT) at Baseline (BL) and Any Time Post-baseline
Measure Description	Participants underwent clinical examination of the breasts, to evaluate for palpable breast tissue. Clinical significance of the results was determined by subjective judgment of the clinical personnel performing the examination.
Time Frame	Baseline; up to 28 months
Safety Issue?	Yes

Analysis Population Description

ITT Population. Only those participants with PBT at baseline or PBT at any time post-baseline were measured for clinical significance.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	147	147
Number of Participants With Palpable Breast Tissue (PBT) at Baseline (BL) and Any Time Post-baseline [units: participants]		
BL; PBT, n=147, 147	6	4
BL; Clinically significant (CS) PBT, n=6, 4	0	0
No BL PBT, but PBT at any time post-BL, n=147,147	10	21
CS change in PBT; BL to any time post-BL, n=10, 21	0	4

21. Secondary Outcome Measure:

Measure Title	Number of Participants With Nipple Tenderness (NT) at Baseline (BL) and Any Time Post-baseline
Measure Description	Participants underwent clinical examination of the breasts, to evaluate for nipple tenderness. Clinical significance of the results was determined by subjective judgment of the clinical personnel performing the examination.
Time Frame	Baseline; up to 28 months

Safety Issue?	Yes

Analysis Population Description

ITT Population. Only those participants with NT at baseline or NT at any time post-baseline were measured for clinical significance.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	147	147
Number of Participants With Nipple Tenderness (NT) at Baseline (BL) and Any Time Post-baseline [units: participants]		
BL; NT, n=147, 147	0	3
BL; Clinically significant (CS) NT, n=0, 3	0	0
No NT at BL, but NT at any time post-BL, n=147,147	8	11
CS change in NT; BL to any time post-BL, n=8, 11	0	1

22. Secondary Outcome Measure:

Measure Title	Number of Participants With a Digital Rectal Examination (DRE) Evaluation Changing From Normal/Diffusely Enlarged at Baseline to Focal Abnormality at Any Time Post-baseline
Measure Description	Participants underwent a digital rectal examination to evaluate for focal abnormality of the prostate.
Time Frame	Baseline; up to 28 months
Safety Issue?	Yes

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	147	147
Number of Participants With a Digital Rectal Examination (DRE) Evaluation Changing From Normal/Diffusely Enlarged at Baseline to Focal Abnormality at Any Time Post-baseline [units: participants]	10	8

23. Secondary Outcome Measure:

Measure Title	Number of Participants With Threshold Vital Signs at Baseline and Any Time Post-baseline
Measure Description	Threshold vital signs are defined as follows: < 80 mmHg or > 165 mmHg for systolic blood pressure; < 40 mmHg or > 105 mm Hg for diastolic blood pressure, < 40 beats per minute (bpm) or > 100 bpm for heart rate.
Time Frame	Baseline; up to 28 months
Safety Issue?	Yes

Analysis Population Description

ITT Population. Participants not having a baseline as well as a post-baseline measurement of at least one vital sign parameter were excluded from this analysis (6 in placebo arm, 4 in dutasteride arm).

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed	141	143

	Placebo	Dutasteride 0.5 mg
Number of Participants With Threshold Vital Signs at Baseline and Any Time Post-baseline [units: participants]		
Baseline	18	15
Any time post-baseline	37	36

Reported Adverse Events

Time Frame	Serious adverse events (SAEs) and non-serious AEs were collected from Baseline to the End of Study (up to 28 months after treatment start).
Additional Description	All safety analyses were performed using the ITT Population.

Reporting Groups

	Description
Placebo	Oral dose of 0.5 milligrams (mg) matching placebo capsule once daily for 2 years
Dutasteride 0.5 mg	Oral dose of 0.5 mg dutasteride capsule once daily for 2 years

Serious Adverse Events

	Placebo	Dutasteride 0.5 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	16/147 (10.88%)	16/147 (10.88%)
Blood and lymphatic system disorders		
Anaemia [A] †	0/147 (0%)	1/147 (0.68%)
Cardiac disorders		
Acute coronary syndrome [A] †	1/147 (0.68%)	0/147 (0%)
Arrhythmia [A] †	1/147 (0.68%)	1/147 (0.68%)
Atrial fibrillation [A] †	1/147 (0.68%)	1/147 (0.68%)

	Placebo	Dutasteride 0.5 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Cardiac failure congestive [A] †	0/147 (0%)	1/147 (0.68%)
Myocardial infarction [A] †	0/147 (0%)	1/147 (0.68%)
Sinus bradycardia [A] †	0/147 (0%)	1/147 (0.68%)
Ventricular tachycardia [A] †	1/147 (0.68%)	0/147 (0%)
Endocrine disorders		
Adrenal insufficiency [A] †	1/147 (0.68%)	0/147 (0%)
Gastrointestinal disorders		
Abdominal wall haematoma [A] †	0/147 (0%)	1/147 (0.68%)
Diarrhoea [A] †	0/147 (0%)	1/147 (0.68%)
Gastric ulcer [A] †	1/147 (0.68%)	0/147 (0%)
Inguinal hernia [A] †	0/147 (0%)	1/147 (0.68%)
General disorders		
Gait disturbance [A] †	1/147 (0.68%)	0/147 (0%)
Hepatobiliary disorders		
Bile duct stone [A] †	0/147 (0%)	1/147 (0.68%)
Infections and infestations		
Bacterial infection [A] †	1/147 (0.68%)	0/147 (0%)
Gastroenteritis [A] †	0/147 (0%)	1/147 (0.68%)
Hepatitis C [A] †	0/147 (0%)	1/147 (0.68%)
Respiratory tract infection [A] †	0/147 (0%)	1/147 (0.68%)
Skin infection [A] †	1/147 (0.68%)	0/147 (0%)
Urethral abscess [A] †	1/147 (0.68%)	0/147 (0%)
Injury, poisoning and procedural complications		

	Placebo	Dutasteride 0.5 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Femur fracture [A] †	0/147 (0%)	1/147 (0.68%)
Spinal fracture [A] †	1/147 (0.68%)	0/147 (0%)
Subdural haematoma [A] †	1/147 (0.68%)	0/147 (0%)
Musculoskeletal and connective tissue disorders		
Osteoarthritis [A] †	1/147 (0.68%)	0/147 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bladder cancer [A] †	1/147 (0.68%)	0/147 (0%)
Bladder cancer recurrent [A] †	1/147 (0.68%)	0/147 (0%)
Bladder neoplasm [A] †	0/147 (0%)	1/147 (0.68%)
Hepatic neoplasm malignant [A] †	0/147 (0%)	1/147 (0.68%)
Lung cancer metastatic [A] †	1/147 (0.68%)	0/147 (0%)
Metastases to bone [A] †	1/147 (0.68%)	0/147 (0%)
Metastases to liver [A] †	1/147 (0.68%)	1/147 (0.68%)
Neoplasm malignant [A] †	0/147 (0%)	1/147 (0.68%)
Non-small cell lung cancer [A] †	1/147 (0.68%)	0/147 (0%)
Prostate cancer metastatic [A] †	1/147 (0.68%)	0/147 (0%)
Nervous system disorders		
Balance disorder [A] †	0/147 (0%)	1/147 (0.68%)
Central nervous system lesion [A] †	1/147 (0.68%)	0/147 (0%)
Cognitive disorder [A] †	1/147 (0.68%)	0/147 (0%)
Dizziness [A] †	1/147 (0.68%)	0/147 (0%)
Intracranial aneurysm [A] †	1/147 (0.68%)	0/147 (0%)

	Placebo	Dutasteride 0.5 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Transient ischaemic attack [A] †	0/147 (0%)	1/147 (0.68%)
Renal and urinary disorders		
Bladder neck sclerosis [A] †	1/147 (0.68%)	0/147 (0%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory failure [A] †	0/147 (0%)	1/147 (0.68%)
Chronic obstructive pulmonary disease [A] †	0/147 (0%)	1/147 (0.68%)
Dyspnoea [A] †	0/147 (0%)	1/147 (0.68%)
Pulmonary embolism [A] †	0/147 (0%)	1/147 (0.68%)
Vascular disorders		
Shock [A] †	0/147 (0%)	1/147 (0.68%)

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

Other Adverse Events

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

	Placebo	Dutasteride 0.5 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	31/147 (21.09%)	32/147 (21.77%)
Infections and infestations		
Nasopharyngitis [A] †	10/147 (6.8%)	14/147 (9.52%)
Musculoskeletal and connective tissue disorders		
Back pain [A] †	11/147 (7.48%)	4/147 (2.72%)
Renal and urinary disorders		
Urinary incontinence [A] †	4/147 (2.72%)	8/147 (5.44%)
Reproductive system and breast disorders		

	Placebo	Dutasteride 0.5 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Gynaecomastia [A] †	4/147 (2.72%)	10/147 (6.8%)
Vascular disorders		
Hypertension [A] †	10/147 (6.8%)	4/147 (2.72%)

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

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.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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