ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 01/25/2012

Adjuvant Leuprolide With or Without Docetaxel in High Risk Prostate Cancer After Radical Prostatectomy

This study has been completed.

Sponsor:	Sanofi
Collaborators:	
Information provided by (Responsible Party):	Sanofi
ClinicalTrials.gov Identifier:	NCT00283062

Purpose

This is a prospective, multicenter, open-label, randomized phase III study in participants at high risk of recurrent prostate cancer after radical prostatectomy. The study will investigate

- Treatment with docetaxel (TAXOTERE®) every three weeks (q3w) plus leuprolide acetate (ELIGARD®) versus leuprolide acetate alone (ELIGARD®)
- Immediate treatment following prostatectomy versus deferred treatment at the time of relapse

Using a 2x2 factorial design participants will therefore be randomized to

- Immediate adjuvant treatment with docetaxel plus leuprolide acetate (chemotherapy and hormonal therapy)
- Immediate adjuvant treatment with leuprolide acetate alone (hormonal therapy)
- Deferred treatment with docetaxel plus leuprolide acetate (chemotherapy and hormonal therapy)
- Deferred treatment with leuprolide acetate alone (hormonal therapy)

Primary Objective:

- The primary objective of the study is to compare progression-free survival using a 2x2 factorial design

Secondary Objectives:

- To compare the 5-year overall, cancer-specific and metastasis-free survival after systemic treatment between the groups
- To compare the safety and tolerability between Docetaxel in combination with leuprolide acetate and leuprolide acetate alone.
- To evaluate quality of life as measured by the FACT-P questionnaire.

Originally, 1696 participants were planned in the study (with 424 participants randomized to each arm). However, only a total of 211 participants completed the randomization procedure as of 26 September 2007. Thus, sanofi-aventis, in accordance with the Steering Committee, decided to stop the participant recruitment as of 26 September 2007. Participants who had already signed their Informed Consent (IC) before September 26, 2007 were allowed to enter the randomization if they met eligibility criteria. The final revised number of planned participants to be randomly assigned to the 4 treatment arms was 250, and 228 participants were actually randomized.

The final sample size did not allow all the statistical analyses to be conducted on efficacy data. Therefore, the protocol was amended to reflect the change in the plans for statistical analysis. The study was underpowered to serve as the basis for drawing conclusions regarding efficacy and quality of life (QoL) endpoints.

Condition	Intervention	Phase
Prostatic Neoplasms	Drug: Docetaxel (TAXOTERE®) Chemotherapy Drug: Leuprolide acetate (ELIGARD®) Hormonal Therapy	Phase 3

Study Type: Interventional
Study Design: Treatment, Factorial Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: A Multicenter, Open-Label, Randomized, Phase III Trial Comparing Immediate Adjuvant Hormonal Therapy (ELIGARD®- Leuprolide Acetate) in Combination With TAXOTERE® (Docetaxel) Administered Every Three Weeks Versus Hormonal Therapy Alone Versus Deferred Therapy Followed by the Same Therapeutic Options in Patients With Prostate Cancer at High Risk of Relapse After Radical Prostatectomy

Further study details as provided by Sanofi:

Primary Outcome Measure:

- Progression-free Survival (PFS) Assessment - Number of Participants With Disease Progression [Time Frame: from the date of surgery up to 3 years after randomization of the last participant] [Designated as safety issue: No]

  PFS is the interval from the date of surgery to date of progression. The date of progression was the earlier of • first PSA increase to ≥ 0.4 ng/mL confirmed within two weeks • date of the nadir, if PSA nadir did not reach < 0.4 ng/mL (for deferred arm) • first radiological/ histological evidence of tumor progression • death. Median PFS was to be estimated using Kaplan-Meier curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Median PFS could not be estimated. Reported is the number of participants with disease progression.

Secondary Outcome Measures:

- Median Overall Survival (OS) [Time Frame: from the date of surgery up to 3 years after randomization of the last participant] [Designated as safety issue: No]

  Overall survival (OS) was the time interval from the date of surgery to the date of death due to any cause. Median OS was to be estimated using Kaplan-Meier Curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Moreover, median OS could not be estimated. Reported is the number of participants who died from any cause.
- Median Cancer-specific Survival (CSS) [Time Frame: from the date of surgery up to 3 years after randomization of the last participant] [Designated as safety issue: No]

  The CSS was the time from the date of surgery to the date of death due to prostate cancer. Median CSS was to be estimated using Kaplan-Meier curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Therefore, based on a protocol amendment, median CSS was not estimated.
- Median Metastasis-free Survival (MFS) [Time Frame: from the date of surgery up to 3 years after randomization of the last participant] [Designated as safety issue: No]

MFS was the interval from the date of surgery to the date of the first clinical evidence of metastasis after treatment initiation. Metastasis was evaluated by a physical exam or radiologically on bone scan or CT scan. Local (palpable) progression, documented histologically or by imaging techniques was considered evidence of progression. Median MFS was to be estimated using Kaplan-Meier curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Therefore, based on a protocol amendment, median MFS was not estimated.

- To Evaluate Quality of Life (QoL) as Measured Using a Functional Assessment of Cancer Therapy-Prostate (FACT-P) Questionnaire [Time Frame: from 30 days before randomization (baseline) and 18 months after treatment initiation (for change from baseline)] [Designated as safety issue: No]
  The FACT-P is a 39-item participant questionnaire which assesses physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and additional prostate cancer specific concerns (12 items). All items are scored from 0 (not at all) to 4 (very much). The total FACT-P score ranges from 0-156, with higher scores representing a better QoL with fewer symptoms. A score of 156 represents the best outcome. Note: Enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn due to the low sample size.
- Assessment of Safety and Tolerability - Number of Participants With Adverse Events (AE) [Time Frame: from treatment initiation up to 19 months after treatment initiation] [Designated as safety issue: Yes]
  Number of participants with treatment-emergent adverse events (TEAE). A TEAE was as any adverse event that occurred or worsened during the on-treatment period, which was the period from the day of first infusion of study treatment until 30 days after the last infusion of study treatment.

Enrollment: 228
Study Start Date: December 2005
Primary Completion Date: December 2010
Study Completion Date: December 2010

Arms	Assigned Interventions
Experimental: Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT) Participants administered docetaxel every three weeks (q3w) for 6 cycles in combination with leuprolide acetate every 3 months for 18 months immediately following prostatectomy.	Drug: Docetaxel (TAXOTERE®) Chemotherapy 75 mg/m^2 docetaxel administered intravenously over 1 hour on Day 1 every three weeks (q3w) for 6 cycles. The first cycle was to be administered within 8 days after randomization. Corticosteroid pre-medication was mandatory. The following schedule was recommended - 8 mg Dexamethasone orally for 6 doses given - the night before chemotherapy, the morning of chemotherapy, 1 hour before docetaxel infusion, the night of chemotherapy, the morning of the day after chemotherapy and the night of the day after chemotherapy. Drug: Leuprolide acetate (ELIGARD®) Hormonal Therapy 22.5 mg leuprolide acetate injection administered subcutaneously (SC) every 3 months for 18 months. The first injection was to be administered within 8 days after randomization.
Active Comparator: Leuprolide Acetate - Immediate Treatment (I-HT)	Drug: Leuprolide acetate (ELIGARD®) Hormonal Therapy 22.5 mg leuprolide acetate injection administered subcutaneously (SC) every 3 months for 18 months.

Arms	Assigned Interventions
Participants administered leuprolide acetate every 3 months for 18 months immediately following prostatectomy.	The first injection was to be administered within 8 days after randomization.
Experimental: Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT) Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with docetaxel every three weeks (q3w) for 6 cycles in combination with leuprolide acetate every 3 months for 18 months.	Drug: Docetaxel (TAXOTERE®) Chemotherapy 75 mg/m^2 docetaxel administered IV over 1 hour on Day 1 q3w for 6 cycles. The first cycle was to be administered within 30 days after progression was confirmed. Corticosteroid pre-medication was mandatory. The following schedule was recommended - 8 mg Dexamethasone orally for 6 doses given - the night before chemotherapy, the morning of chemotherapy, 1 hour before docetaxel infusion, the night of chemotherapy, the morning of the day after chemotherapy and the night of the day after chemotherapy. Drug: Leuprolide acetate (ELIGARD®) Hormonal Therapy 22.5 mg leuprolide acetate injection administered subcutaneously (SC) every 3 months for 18 months. The first injection was to be administered within 30 days after progression is confirmed (on Day 1 of docetaxel administration).
Active Comparator: Leuprolide Acetate - Deferred Treatment (D-HT) Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with with leuprolide acetate every 3 months for 18 months.	Drug: Leuprolide acetate (ELIGARD®) Hormonal Therapy 22.5 mg leuprolide acetate injection administered subcutaneously (SC) every 3 months for 18 months. The first injection was to be administered within 30 days after progression is confirmed.

Detailed Description:

The study consisted of the following:

- Randomization of eligible participants within 120 days of prostatectomy
- For participants assigned to immediate therapy, a treatment period up to 18 months within 8 days of randomization
- For participants assigned to deferred treatment, a treatment period up to 18 months after evidence of progression prior to December 2010. Participants who did not progress before December 2010 were withdrawn from the study.

Eligibility

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

Criteria

Inclusion Criteria:

Participants who met all of the following criteria were considered for enrollment into the study.

- Pathologically confirmed adenocarcinoma of the prostate based on central pathology review. All other variants are excluded
- Randomization should occur less than 120 days after prostatectomy AND lymphadenectomy.
- A predicted probability of 5-year freedom from progression ≤ 60%, as determined by the postoperative nomogram developed by M. Kattan.
- Bone-scan without evidence of metastasis (within 6 months of randomization)
- Chest x-ray without evidence of metastasis (within 6 months of randomization)
- Abdominal computed tomography (CT) Scan without evidence of metastasis (within 6 months of randomization)
- Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
- Hematology evaluation within 2 weeks prior to randomization:
    - Neutrophils ≥ 2,000/mm3
    - Hemoglobin ≥ 10 g/dL
    - Platelets ≥ 100,000/mm3
- Hepatic and renal function evaluation within 2 weeks prior to randomization:
    - Serum creatinine ≤1.5 × Upper normal limit (UNL) for the institution. If serum creatinine is > 1.5 × UNL, calculate creatinine clearance (should be ≥ 60ml/minute).
    - Total serum bilirubin ≤ UNL for the institution. Participants with Gilbert's syndrome may be eligible if indirect serum bilirubin levels at the time of randomization and, at least 6 month prior to randomization, confirm this condition (i.e. elevated indirect serum bilirubin).
    - Serum glutamic oxaloacetic transaminase (SGOT) and/or serum glutamic pyruvic transaminase (SGPT) ≤ 1.5 × institutional UNL if alkaline phosphatase is ≤ UNL OR
    - alkaline phosphatase ≤ 5 × UNL if SGOT and SGPT are ≤ UNL
- Prostate Specific Antigen (PSA) evaluation within 9 months prior to prostatectomy. However, a 120-day timeframe is recommended
- Post operative PSA necessary for eligibility is defined as a level ≤ 0.2ng/mL using a standard assay at least 30 days after radical prostatectomy and within 7 days prior to randomization. Note that randomization should occur within 120 days after radical prostatectomy
- Serum testosterone ≥ 150ng/dL within 6 months prior to randomization.

Exclusion Criteria:

Participants presenting with any of the following will not be included in the study.

- Prior systemic treatment for prostate cancer with hormonal therapy, chemotherapy, or any other anticancer therapy.
- Prior radiation therapy.
- Participants who received, are receiving or scheduled to receive post-operative radiotherapy.
- Participants taking alternative therapies for cancer must stop taking these therapies prior to randomization. Alternative therapies are not allowed during the treatment or follow-up portions of the study. This includes (but is not limited to) alternative therapies such as :

    - PC-SPES (all types)
    - 5-alpha reductase inhibitors
- Bisphosphonates are to be stopped prior to randomization and are not allowed during the study.
- Chronic treatment with corticosteroids unless initiated > 6 months prior to study entry and at low dose (≤ 20 mg methylprednisolone per day or equivalent).
- History of a malignancy other than prostate cancer. Exceptions to these criteria include:
    - participants with adequately treated non-melanoma skin cancers, and
    - participants with a history of another malignancy that was curatively treated (including participants with superficial bladder cancer) and who have not had evidence of disease for a minimum of 5 years.
- Peripheral neuropathy ≥ Grade 2.
- Electrocardiogram (ECG) with significant abnormalities (as determined by the investigator) within 90 days prior to randomization.
- Participants who are medically unstable, including but not limited to active infection, acute hepatitis, gastrointestinal bleeding, uncontrolled cardiac arrhythmias, interstitial lung disease, inflammatory bowel disease, uncontrolled angina, uncontrolled hypercalcemia, uncompensated congestive heart failure, uncontrolled diabetes, dementia, seizures, superior vena cava syndrome.
- Participants with history of hypersensitivity to polysorbate 80.
- Participants with a known history of viral hepatitis (B, C).

The above information was not intended to contain all considerations relevant to potential participation in a clinical trial.

Contacts and Locations

Locations

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Sao Paulo, Brazil

Canada

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Québec, Canada

France

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Paris, France

Germany

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Investigators

Study Director:	Jean-Philippe Aussel	sanofi-aventis

More Information

Responsible Party:	Sanofi
Study ID Numbers:	XRP6976J_3501 EudraCT # : 2004-002203-32
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Participant Flow

Recruitment Details	Originally, the study was planned for 1696 participants to be randomized. However, enrollment was not met and in September 2007, the Steering Committee decided to stop recruitment. Only participants who had signed Informed Consent by then and met eligibility criteria were randomized. 228 participants were randomized to this study.

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Overall Study

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Started	55	55	56	62
ADMINISTERED STUDY TREATMENT	50	51	20	17
COMPLETED HORMONAL THERAPY (6 Cycles)	44	48	15	13
COMPLETED CHEMOTHERAPY (6 Cycles)	43	0 [1]	15	0 [1]
Completed	43	48	15	13
Not Completed	12	7	41	49
Did not receive any study medication	5	4	36	45

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Adverse Event	2	0	1	0
Lost to Follow-up	1	0	1	0
Progressive disease	0	0	1	0
Participant did not wish to continue	3	2	1	0
Undefined	0	1	1	4
chemotherapy not completed (cycle 6)	1	0	0	0

[1] Not applicable, since participants in this arm did not receive chemotherapy.

Baseline Characteristics

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Baseline Measures

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)	Total
Number of Participants	55	55	56	62	228

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)	Total
Age, Continuous [units: years] Mean (Standard Deviation)	61.2 (7.4)	61.6 (7.0)	62.1 (7)	62.9 (7.5)	61.9 (7.2)
Age, Customized [units: participants]					
<65 years	37	34	35	35	141
>=65 years	18	21	21	27	87
Gender, Male/Female [units: participants]					
Female	0	0	0	0	0
Male	55	55	56	62	228
Race/Ethnicity, Customized [units: participants]					
White	48	49	43	59	199
Black	6	3	7	2	18
Asian/Oriental	0	1	4	0	5
Multiracial	0	0	2	0	2
Other	1	2	0	1	4

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression-free Survival (PFS) Assessment - Number of Participants With Disease Progression
Measure Description	PFS is the interval from the date of surgery to date of progression. The date of progression was the earlier of • first PSA increase to ≥ 0.4 ng/mL confirmed within two weeks • date of the nadir, if PSA nadir did not reach < 0.4 ng/mL (for deferred arm) • first radiological/ histological evidence of tumor progression • death. Median PFS was to be estimated using Kaplan-Meier curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Median PFS could not be estimated. Reported is the number of participants with disease progression.
Time Frame	from the date of surgery up to 3 years after randomization of the last participant

Safety Issue?	No

Analysis Population Description

Intent-to-treat (ITT) population: all randomized participants, regardless of whether or not they received any study drug.

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Measured Values

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Number of Participants Analyzed	55	55	56	62
Progression-free Survival (PFS) Assessment - Number of Participants With Disease Progression [units: participants]	10	14	9	8

2. Secondary Outcome Measure:

Measure Title	Median Overall Survival (OS)
Measure Description	Overall survival (OS) was the time interval from the date of surgery to the date of death due to any cause. Median OS was to be estimated using Kaplan-Meier Curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Moreover, median OS could not be estimated. Reported is the number of participants who died from any cause.

Time Frame	from the date of surgery up to 3 years after randomization of the last participant
Safety Issue?	No

Analysis Population Description

Intent-to-treat (ITT) population: all randomized participants, regardless of whether or not they received any drug.

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Measured Values

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Number of Participants Analyzed	55	55	56	62
Median Overall Survival (OS) [units: participants]	0	2	1	1

3. Secondary Outcome Measure:

Measure Title	Median Cancer-specific Survival (CSS)
Measure Description	The CSS was the time from the date of surgery to the date of death due to prostate cancer. Median CSS was to be estimated using Kaplan-Meier curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Therefore, based on a protocol amendment, median CSS was not estimated.

Time Frame	from the date of surgery up to 3 years after randomization of the last participant
Safety Issue?	No

Analysis Population Description

Based on a protocol amendment, analysis for Median CSS was not to be performed as the study was underpowered.

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Measured Values

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

Measure Title	Median Metastasis-free Survival (MFS)
Measure Description	MFS was the interval from the date of surgery to the date of the first clinical evidence of metastasis after treatment initiation. Metastasis was evaluated by a physical exam or radiologically on bone scan or CT scan. Local (palpable) progression, documented histologically or by imaging techniques was considered evidence of progression. Median MFS was to be estimated using Kaplan-Meier curves. However, enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn. Therefore, based on a protocol amendment, median MFS was not estimated.

Time Frame	from the date of surgery up to 3 years after randomization of the last participant
Safety Issue?	No

Analysis Population Description

Based on a protocol amendment, analysis for Median MFS was not to be performed as the study was underpowered.

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Measured Values

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome Measure:

Measure Title	To Evaluate Quality of Life (QoL) as Measured Using a Functional Assessment of Cancer Therapy-Prostate (FACT-P) Questionnaire

Measure Description	The FACT-P is a 39-item participant questionnaire which assesses physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and additional prostate cancer specific concerns (12 items). All items are scored from 0 (not at all) to 4 (very much). The total FACT-P score ranges from 0-156, with higher scores representing a better QoL with fewer symptoms. A score of 156 represents the best outcome. Note: Enrollment was not met, and meaningful conclusions for efficacy or QoL could not be drawn due to the low sample size.
Time Frame	from 30 days before randomization (baseline) and 18 months after treatment initiation (for change from baseline)
Safety Issue?	No

Analysis Population Description

QoL population: The subset of randomized participants who had an evaluable baseline questionnaire and at least one evaluable post-baseline questionnaire. A baseline QoL questionnaire was considered evaluable if it was filled out within 30 days prior to randomization, and no later than the date of randomization.

Reporting Groups

	Description
Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Measured Values

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Number of Participants Analyzed	40	48	15	15
To Evaluate Quality of Life (QoL) as Measured Using a Functional Assessment of Cancer Therapy-Prostate (FACT-P) Questionnaire [units: score on a scale] Mean (Standard Deviation)				

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Baseline	124.0 (6.0)	121.5 (17.8)	114.7 (13.9)	119.7 (15.8)
Change from Baseline (N=33, N=41, N=12, N=10)	0.7 (12.6)	1.7 (17.2)	6.7 (15.9)	6.1 (18.9)

6. Secondary Outcome Measure:

Measure Title	Assessment of Safety and Tolerability - Number of Participants With Adverse Events (AE)
Measure Description	Number of participants with treatment-emergent adverse events (TEAE). A TEAE was as any adverse event that occurred or worsened during the on-treatment period, which was the period from the day of first infusion of study treatment until 30 days after the last infusion of study treatment.
Time Frame	from treatment initiation up to 19 months after treatment initiation
Safety Issue?	Yes

Analysis Population Description

Safety population: all randomized participants who received any study drug

Reporting Groups

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Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Participants administered 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Measured Values

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
Number of Participants Analyzed	50	51	20	17
Assessment of Safety and Tolerability - Number of Participants With Adverse Events (AE) [units: participants]				
with any adverse event (AE)	47	48	19	14
with any serious adverse event (SAE)	12	8	5	2
with an SAE resulting in death	0	0	0	0
with a drug-related AE	47	43	18	10
with a drug-related SAE	6	0	2	0
with AE leading to discontinue all study therapy	2	0	1	0
with AE leading to chemotherapy discontinuation	1	NA [1]	1	NA [1]
with AE leading to chemotherapy dose reduction	5	NA [1]	2	NA [1]

[1] Did not receive chemotherapy

Reported Adverse Events

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

Reporting Groups

	Description
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Leuprolide Acetate - Immediate Treatment (I-HT)	Participants administered 22.5 mg leuprolide acetate every 3 months for 18 months immediately following prostatectomy.

	Description
Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 75 mg/m^2 docetaxel every three weeks (q3w) for 6 cycles in combination with 22.5 mg leuprolide acetate every 3 months for 18 months.
Leuprolide Acetate - Deferred Treatment (D-HT)	Participants in whom treatment was deferred from randomization until first progression - i.e. PSA progression and/or radiologically or histologically documented progression. Participants were treated with 22.5 mg leuprolide acetate every 3 months for 18 months.

Serious Adverse Events

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	12/50 (24%)	8/51 (15.69%)	5/20 (25%)	2/17 (11.76%)
Blood and lymphatic system disorders				
Febrile neutropenia [A] *	3/50 (6%)	0/51 (0%)	2/20 (10%)	0/17 (0%)
Neutropenia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Cardiac disorders				
Coronary artery disease [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Eye disorders				
Optic neuropathy [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Gastrointestinal disorders				
Colitis [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Diarrhoea [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Haemorrhoidal haemorrhage [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Hernial eventration [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Inguinal hernia [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Rectal haemorrhage [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
General disorders				

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Extravasation [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Fatigue [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Oedema peripheral [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Pyrexia [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Infections and infestations				
Bronchitis [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Diverticulitis [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Injury, poisoning and procedural complications				
Face injury [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Facial bones fracture [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Foot fracture [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Subdural haematoma [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Investigations				
Blood cholesterol increased [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Blood glucose increased [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Blood triglycerides increased [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Arthropathy [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Pain in extremity [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Respiratory tract neoplasm [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nervous system disorders				
Carpal tunnel syndrome [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Dizziness [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Transient ischaemic attack [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Renal and urinary disorders				
Renal colic [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Urinary incontinence [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDra 13.1

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	47/50 (94%)	48/51 (94.12%)	19/20 (95%)	13/17 (76.47%)
Blood and lymphatic system disorders				
Febrile neutropenia [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Lymphopenia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Cardiac disorders				
Diastolic dysfunction [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Nodal arrhythmia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Palpitations [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Sinus tachycardia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Tachycardia [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Congenital, familial and genetic disorders				
Phimosis [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Thalassaemia [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Ear and labyrinth disorders				
Deafness [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Hearing impaired [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Tinnitus [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	1/17 (5.88%)
Eye disorders				
Blepharitis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Cataract [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Conjunctivitis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Eye haemorrhage [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Eye pain [A] *	2/50 (4%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Eye pruritus [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Eyelid oedema [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Glaucoma [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Keratoconjunctivitis sicca [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Lacrimal disorder [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Lacrimation increased [A] *	4/50 (8%)	0/51 (0%)	2/20 (10%)	0/17 (0%)
Ocular hyperaemia [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Optic neuropathy [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Retinal detachment [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Retinopathy [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Vision blurred [A] *	4/50 (8%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Gastrointestinal disorders				
Abdominal discomfort [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Abdominal distension [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Abdominal hernia [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Abdominal pain [A] *	2/50 (4%)	1/51 (1.96%)	1/20 (5%)	1/17 (5.88%)
Abdominal pain lower [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Abdominal pain upper [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Anorectal discomfort [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Buccal mucosal roughening [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Constipation [A] *	10/50 (20%)	1/51 (1.96%)	4/20 (20%)	0/17 (0%)
Diarrhoea [A] *	14/50 (28%)	2/51 (3.92%)	6/20 (30%)	0/17 (0%)
Dry mouth [A] *	3/50 (6%)	1/51 (1.96%)	2/20 (10%)	1/17 (5.88%)
Dyspepsia [A] *	5/50 (10%)	1/51 (1.96%)	2/20 (10%)	0/17 (0%)
Dysphagia [A] *	2/50 (4%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Flatulence [A] *	3/50 (6%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Gastritis [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Gastrointestinal haemorrhage [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastrooesophageal reflux disease [A] *	2/50 (4%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Glossodynia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Haemorrhoids [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Inguinal hernia [A] *	2/50 (4%)	3/51 (5.88%)	1/20 (5%)	0/17 (0%)
Mouth ulceration [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Nausea [A] *	16/50 (32%)	4/51 (7.84%)	4/20 (20%)	1/17 (5.88%)
Oral discomfort [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Paraesthesia oral [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Rectal haemorrhage [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Sensitivity of teeth [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Sigmoiditis [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Stomatitis [A] *	7/50 (14%)	0/51 (0%)	2/20 (10%)	0/17 (0%)
Tongue discolouration [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Toothache [A] *	0/50 (0%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Vomiting [A] *	3/50 (6%)	2/51 (3.92%)	2/20 (10%)	0/17 (0%)
General disorders				
Asthenia [A] *	5/50 (10%)	3/51 (5.88%)	5/20 (25%)	1/17 (5.88%)
Chest discomfort [A] *	3/50 (6%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Chest pain [A] *	1/50 (2%)	0/51 (0%)	2/20 (10%)	0/17 (0%)
Chills [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Cyst [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Discomfort [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Extravasation [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Face oedema [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Fatigue [A] *	32/50 (64%)	16/51 (31.37%)	13/20 (65%)	3/17 (17.65%)
Induration [A] *	3/50 (6%)	2/51 (3.92%)	1/20 (5%)	0/17 (0%)
Influenza like illness [A] *	2/50 (4%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Infusion site extravasation [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injection site discolouration [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Injection site discomfort [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injection site erythema [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injection site nodule [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injection site pain [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	1/17 (5.88%)
Injection site rash [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injection site reaction [A] *	3/50 (6%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injection site swelling [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Localised oedema [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Mucosal inflammation [A] *	4/50 (8%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Necrosis [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Nodule [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Oedema peripheral [A] *	12/50 (24%)	4/51 (7.84%)	5/20 (25%)	0/17 (0%)
Pain [A] *	4/50 (8%)	0/51 (0%)	1/20 (5%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pyrexia [A] *	5/50 (10%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Temperature intolerance [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Tenderness [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Thirst [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Immune system disorders				
Drug hypersensitivity [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Hypersensitivity [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Multiple allergies [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Infections and infestations				
Abscess [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Anal infection [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Bronchitis [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	1/17 (5.88%)
Campylobacter intestinal infection [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Cellulitis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Erysipelas [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Escherichia urinary tract infection [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Eye infection [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Gastroenteritis viral [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Genital infection fungal [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Herpes simplex [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Herpes simplex ophthalmic [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Herpes zoster [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Hordeolum [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Infection [A] *	4/50 (8%)	1/51 (1.96%)	0/20 (0%)	1/17 (5.88%)
Influenza [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Lip infection [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Nasopharyngitis [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Neutropenic infection [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Oral candidiasis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Otitis externa [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Pharyngitis [A] *	0/50 (0%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Pyelonephritis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Rhinitis [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Sinusitis [A] *	1/50 (2%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Skin candida [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Tooth abscess [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Upper respiratory tract infection [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Urinary tract infection [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	1/17 (5.88%)
Viral infection [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Injury, poisoning and procedural complications				
Contusion [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Excoriation [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Eye penetration [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Foot fracture [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Injury [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Nail avulsion [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Procedural complication [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Seroma [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Vascular injury [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Investigations				
Blood cholesterol increased [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Blood glucose increased [A] *	1/50 (2%)	1/51 (1.96%)	1/20 (5%)	0/17 (0%)
Blood pressure increased [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Blood urea increased [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Blood urine [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Body temperature fluctuation [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Bone density decreased [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Cardiac murmur [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Gamma-glutamyltransferase [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Weight decreased [A] *	2/50 (4%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Weight increased [A] *	6/50 (12%)	8/51 (15.69%)	3/20 (15%)	2/17 (11.76%)
Metabolism and nutrition disorders				
Decreased appetite [A] *	4/50 (8%)	2/51 (3.92%)	2/20 (10%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Diabetes mellitus [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Fluid retention [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Hypercalcaemia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Hypercholesterolaemia [A] *	2/50 (4%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Hyperglycaemia [A] *	4/50 (8%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Hyperkalaemia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Hypertriglyceridaemia [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Hypoglycaemia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Increased appetite [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] *	6/50 (12%)	7/51 (13.73%)	5/20 (25%)	0/17 (0%)
Arthritis [A] *	1/50 (2%)	1/51 (1.96%)	1/20 (5%)	0/17 (0%)
Back pain [A] *	7/50 (14%)	3/51 (5.88%)	5/20 (25%)	1/17 (5.88%)
Bone pain [A] *	3/50 (6%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Flank pain [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Groin pain [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Joint lock [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Joint stiffness [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Limb discomfort [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Muscle spasms [A] *	2/50 (4%)	2/51 (3.92%)	1/20 (5%)	0/17 (0%)
Muscle twitching [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Muscular weakness [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Musculoskeletal chest pain [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Musculoskeletal pain [A] *	1/50 (2%)	3/51 (5.88%)	1/20 (5%)	0/17 (0%)
Myalgia [A] *	4/50 (8%)	5/51 (9.8%)	4/20 (20%)	0/17 (0%)
Neck pain [A] *	0/50 (0%)	4/51 (7.84%)	0/20 (0%)	0/17 (0%)
Osteoarthritis [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Osteopenia [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Osteoporosis [A] *	1/50 (2%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Pain in extremity [A] *	9/50 (18%)	4/51 (7.84%)	2/20 (10%)	1/17 (5.88%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Keratoacanthoma [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Squamous cell carcinoma of skin [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Nervous system disorders				
Ageusia [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Amnesia [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Aphasia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Burning sensation [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Carpal tunnel syndrome [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Disturbance in attention [A] *	2/50 (4%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Dizziness [A] *	5/50 (10%)	2/51 (3.92%)	3/20 (15%)	0/17 (0%)
Dysgeusia [A] *	17/50 (34%)	0/51 (0%)	5/20 (25%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Headache [A] *	14/50 (28%)	3/51 (5.88%)	3/20 (15%)	0/17 (0%)
Hyperaesthesia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Hypoaesthesia [A] *	5/50 (10%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Hypogeusia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Lethargy [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Neuropathy peripheral [A] *	2/50 (4%)	1/51 (1.96%)	2/20 (10%)	0/17 (0%)
Paraesthesia [A] *	6/50 (12%)	1/51 (1.96%)	2/20 (10%)	0/17 (0%)
Peripheral sensory neuropathy [A] *	12/50 (24%)	2/51 (3.92%)	0/20 (0%)	1/17 (5.88%)
Restless legs syndrome [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Sciatica [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Sensory loss [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Sinus headache [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Tremor [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Psychiatric disorders				
Affect lability [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Anxiety [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Claustrophobia [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Confusional state [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Depression [A] *	3/50 (6%)	3/51 (5.88%)	2/20 (10%)	1/17 (5.88%)
Emotional distress [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Insomnia [A] *	6/50 (12%)	5/51 (9.8%)	1/20 (5%)	1/17 (5.88%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Libido decreased [A] *	2/50 (4%)	4/51 (7.84%)	0/20 (0%)	2/17 (11.76%)
Mood altered [A] *	4/50 (8%)	3/51 (5.88%)	1/20 (5%)	1/17 (5.88%)
Nervousness [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Sleep disorder [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Renal and urinary disorders				
Bladder pain [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Dysuria [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Haematuria [A] *	1/50 (2%)	2/51 (3.92%)	1/20 (5%)	0/17 (0%)
Micturition urgency [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Nephrolithiasis [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Nocturia [A] *	3/50 (6%)	4/51 (7.84%)	1/20 (5%)	0/17 (0%)
Pollakiuria [A] *	2/50 (4%)	6/51 (11.76%)	0/20 (0%)	0/17 (0%)
Renal cyst [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Stress urinary incontinence [A] *	1/50 (2%)	3/51 (5.88%)	1/20 (5%)	0/17 (0%)
Terminal dribbling [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Ureteric stenosis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Urethral obstruction [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Urinary incontinence [A] *	15/50 (30%)	14/51 (27.45%)	0/20 (0%)	2/17 (11.76%)
Urinary retention [A] *	1/50 (2%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Urinary tract disorder [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Reproductive system and breast disorders				

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Ejaculation disorder [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Erectile dysfunction [A] *	15/50 (30%)	17/51 (33.33%)	1/20 (5%)	1/17 (5.88%)
Genital lesion [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Gynaecomastia [A] *	0/50 (0%)	2/51 (3.92%)	2/20 (10%)	0/17 (0%)
Nipple pain [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Oedema genital [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Penile pain [A] *	0/50 (0%)	1/51 (1.96%)	1/20 (5%)	0/17 (0%)
Perineal pain [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Testicular atrophy [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Respiratory, thoracic and mediastinal disorders				
Bronchial obstruction [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Chronic obstructive pulmonary disease [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Cough [A] *	3/50 (6%)	2/51 (3.92%)	1/20 (5%)	0/17 (0%)
Dry throat [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Dyspnoea [A] *	6/50 (12%)	1/51 (1.96%)	3/20 (15%)	0/17 (0%)
Epistaxis [A] *	4/50 (8%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Hiccups [A] *	5/50 (10%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Nasal congestion [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Nasal discomfort [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Nasal disorder [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Oropharyngeal pain [A] *	3/50 (6%)	0/51 (0%)	0/20 (0%)	0/17 (0%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pulmonary embolism [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Rales [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Rhinitis allergic [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Skin and subcutaneous tissue disorders				
Alopecia [A] *	29/50 (58%)	0/51 (0%)	9/20 (45%)	0/17 (0%)
Blister [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Dermal cyst [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Dermatitis [A] *	0/50 (0%)	2/51 (3.92%)	1/20 (5%)	0/17 (0%)
Dermatitis contact [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Dry skin [A] *	7/50 (14%)	1/51 (1.96%)	1/20 (5%)	0/17 (0%)
Eczema [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	1/17 (5.88%)
Erythema [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Erythema multiforme [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Exfoliative rash [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)
Hair disorder [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Hair growth abnormal [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Hyperhidrosis [A] *	7/50 (14%)	3/51 (5.88%)	0/20 (0%)	0/17 (0%)
Hyperkeratosis palmaris and plantaris [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Nail discolouration [A] *	3/50 (6%)	0/51 (0%)	2/20 (10%)	0/17 (0%)
Nail disorder [A] *	14/50 (28%)	0/51 (0%)	6/20 (30%)	0/17 (0%)
Night sweats [A] *	2/50 (4%)	0/51 (0%)	1/20 (5%)	1/17 (5.88%)

	Docetaxel / Leuprolide Acetate - Immediate Treatment (I-CHT)	Leuprolide Acetate - Immediate Treatment (I-HT)	Docetaxel / Leuprolide Acetate - Deferred Treatment (D-CHT)	Leuprolide Acetate - Deferred Treatment (D-HT)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Onychoclasis [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Onychomadesis [A] *	0/50 (0%)	0/51 (0%)	2/20 (10%)	0/17 (0%)
Pain of skin [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Palmar-plantar erythrodysaesthesia syndrome [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Pruritus [A] *	2/50 (4%)	2/51 (3.92%)	0/20 (0%)	0/17 (0%)
Rash [A] *	6/50 (12%)	2/51 (3.92%)	4/20 (20%)	0/17 (0%)
Rash erythematous [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Skin disorder [A] *	1/50 (2%)	0/51 (0%)	0/20 (0%)	0/17 (0%)
Urticaria [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Vascular disorders				
Flushing [A] *	4/50 (8%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Hot flush [A] *	36/50 (72%)	38/51 (74.51%)	11/20 (55%)	8/17 (47.06%)
Hypertension [A] *	6/50 (12%)	2/51 (3.92%)	2/20 (10%)	0/17 (0%)
Hypotension [A] *	1/50 (2%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Intermittent claudication [A] *	0/50 (0%)	1/51 (1.96%)	0/20 (0%)	0/17 (0%)
Peripheral coldness [A] *	0/50 (0%)	0/51 (0%)	1/20 (5%)	0/17 (0%)
Venous insufficiency [A] *	0/50 (0%)	0/51 (0%)	0/20 (0%)	1/17 (5.88%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDra 13.1

Limitations and Caveats

The study had difficulties in meeting enrollment goals within a reasonable time frame. The final sample size allowed for the safety analyses but was underpowered for drawing conclusions regarding efficacy and quality of life (QoL) endpoints.

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 investigator shall provide the Steering Committee a copy of any manuscript, abstract or oral communication derived from the study for review and comment at least 30 days in advance of any submission. The Sponsor's representatives shall have the right to review and/or delay any publication or presentation to prevent disclosure of Sponsor's confidential information and preserve intellectual property rights.

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