Clinical trial results:
Prostate Cancer Antigen-3 (PCA-3) and TMPRSS2-ERG Score changes during initiation of Androgen Deprivation Therapy (ADT) with triptorelin (22.5 mg) in patients with advanced prostate cancer (PCa): A phase III, single arm multicentre study

Summary

EudraCT number	2009-012786-58
Trial protocol	GB ES LV FR NL LT BE IT
Global end of trial date	28 June 2013

Results information

Result version number	v2 (current)
This version publication date	26 February 2016
First version publication date	03 July 2015
Version creation reason	• Correction of full data set Review and correction.

Trial information

Trial identification

Sponsor protocol code	8-79-52014-168

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01020448
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen Pharma sas
Sponsor organisation address	65, quai Georges Gorse, Boulogne-Billancourt, France, F-92100
Public contact	Medical Director, Oncology, Ipsen Pharma sas, clinical.trials@ipsen.com
Scientific contact	Medical Director, Oncology, Ipsen Pharma sas, clinical.trials@ipsen.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 September 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 November 2011
Global end of trial reached?	Yes
Global end of trial date	28 June 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To model the PCA-3 change at Month 6 (M6) post treatment assessment.

Protection of trial subjects:

In compliance with Good Clinical Practice (GCP), the medical records/medical notes etc. had to be clearly marked and permit easy identification of a patient's participation in the specified clinical trial. The dose of triptorelin sustained release (SR) 22.5 mg used in this study has been previously investigated in a multicentre, non-comparative phase III study in patients with advanced PCa.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 November 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 14
Country: Number of subjects enrolled	Romania: 34
Country: Number of subjects enrolled	Spain: 36
Country: Number of subjects enrolled	United Kingdom: 51
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	Denmark: 24
Country: Number of subjects enrolled	France: 89
Country: Number of subjects enrolled	Latvia: 26
Country: Number of subjects enrolled	Lithuania: 41
Worldwide total number of subjects	325
EEA total number of subjects	325

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	60
From 65 to 84 years	245
85 years and over	20

Subject disposition

Recruitment

Recruitment details:

Study Initiation Date: 30-Nov-2009. Subjects screened were 339 and screen failures were 13.

Pre-assignment

Screening details:

326 of the 339 patients screened for this study were included; one patient was excluded from the safety population as no post-baseline assessment was available. The other 325 patients were included in the treatment group.

Period 1

Period 1 title	Triptorelin (Decapeptyl®) 22.5 mg (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Triptorelin (Decapeptyl®) 22.5 mg

Arm description:

Triptorelin (Decapeptyl®): One intramuscular injection of triptorelin (Decapeptyl®) 22.5 mg performed once all baseline procedures and assessments have been completed.

Arm type	Experimental
Investigational medicinal product name	Triptorelin (Decapeptyl®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One intramuscular injection of triptorelin (Decapeptyl®) 22.5mg performed once all baseline procedures and assessments have been completed.

Number of subjects in period 1	Triptorelin (Decapeptyl®) 22.5 mg
Started	325
Completed	299
Not completed	26
Consent withdrawn by subject	3
Adverse event, non-fatal	11
Lost to follow-up	2
Disease Progression	2
Lack of efficacy	8

Baseline characteristics

Reporting groups	
Reporting group title	Triptorelin (Decapeptyl®) 22.5 mg

Reporting group description: -

Reporting group values	Triptorelin (Decapeptyl®) 22.5 mg	Total	
Number of subjects	325	325	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	60	60	
From 65-84 years	245	245	
85 years and over	20	20	
Age continuous			
Units: years			
arithmetic mean	72.6		
standard deviation	± 8.4	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	325	325	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	7	7	
White	307	307	
More than one race	0	0	
Unknown or Not Reported	10	10	
PCA-3 Score			
PCA-3 score = (mRNA PCA3/mRNA PSA)x1000 • Non-assessable = Associated PSA mRNA <7500 copies/mL • ≤BLQ = PCA-3 mRNA is below the concentration of the calibrator and associated PSA mRNA >7500 copies/mL • <35 = PCA-3 mRNA above BLQ and less than 35 • ≥35 = PCA-3 mRNA greater or equal to 35			
Units: Subjects			
Non-assessable	39	39	
≤BLQ	15	15	
<35	89	89	

≥35	179	179	
Missing - No sample analysis done	3	3	

Height			
n=315, missing=10			
Units: Cm			
arithmetic mean	172.3		
standard deviation	± 6.5	-	
Weight			
n=317, missing=8			
Units: KG			
arithmetic mean	79.6		
standard deviation	± 13.4	-	
BMI			
n=314, missing=11			
Units: kg/m²			
arithmetic mean	26.79		
standard deviation	± 4.23	-	

End points

End points reporting groups

Reporting group title	Triptorelin (Decapeptyl®) 22.5 mg

Reporting group description:

Triptorelin (Decapeptyl®): One intramuscular injection of triptorelin (Decapeptyl®) 22.5 mg performed once all baseline procedures and assessments have been completed.

Primary: PCA3 Score Expressed as a Ratio of PCA3 mRNA (Messenger Ribonucleic Acid) Over PSA (Prostate Specific Antigen) mRNA

End point title	PCA3 Score Expressed as a Ratio of PCA3 mRNA (Messenger Ribonucleic Acid) Over PSA (Prostate Specific Antigen) mRNA[1]

End point description:

PCA-3 score = (mRNA PCA3/mRNA PSA)x1000
- Non-assessable = Associated PSA mRNA <7500 copies/mL
- ≤BLQ = PCA-3 mRNA is below the concentration of the calibrator and associated PSA mRNA >7500 copies/mL
- <35 = PCA-3 mRNA above BLQ and less than 35
- ≥35 = PCA-3 mRNA greater or equal to 35

Number of participants analyzed were 298 as one participant was admitted to an asylum and was withdrawn before month 1 visit was scheduled. No postbaseline assessment was available for this patient.

End point type	Primary

End point timeframe:

At month 6 post-treatment

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis for this endpoint

End point values	Triptorelin (Decapeptyl®) 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	298			
Units: Number of subjects analysed				
Non-assessable	232			
≤BLQ	27			
<35	10			
≥35	24			
Missing - No sample analysis done	5			

Statistical analyses

No statistical analyses for this end point

Secondary: PCA3 Score Expressed as a Ratio of PCA3 mRNA Over PSA mRNA

End point title	PCA3 Score Expressed as a Ratio of PCA3 mRNA Over PSA mRNA

End point description:

PCA-3 score = (mRNA PCA3/mRNA PSA)x1000
• Non-assessable = Associated PSA mRNA <7500 copies/mL
• ≤BLQ = PCA-3 mRNA is below the concentration of the calibrator and associated PSA mRNA >7500 copies/mL
• <35 = PCA-3 mRNA above BLQ and less than 35
• ≥35 = PCA-3 mRNA greater or equal to 35

Analysis based on number (N) of patients with a valid value. Intention-to-treat (ITT) population.

End point type	Secondary

End point timeframe:

At month 1 and 3 post-treatment

End point values	Triptorelin (Decapeptyl®) 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	322			
Units: Number of Participants				
Month 1: Non-assessable (N=322)	109			
Month 1: ≤BLQ (N=322)	40			
Month 1: <35 (N=322)	80			
Month 1: ≥35 (N=322)	91			
Month 1: Missing-No sample analysis done (N=322)	2			
Month 3: Non-assessable (N=313)	215			
Month 3: ≤BLQ (N=313)	31			
Month 3: <35 (N=313)	34			
Month 3: ≥35 (N=313)	31			
Month 3: Missing-No sample analysis done (N=313)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: TMPRSS2-ERG Score (Expressed as a Ratio of T2-ERG mRNA Over PSA mRNA)

End point title	TMPRSS2-ERG Score (Expressed as a Ratio of T2-ERG mRNA Over PSA mRNA)

End point description:

TMPRSS2-ERG = (TMPRSS2-ERG mRNA / PSA mRNA) x 100000
A TMPRSS2-ERG score <35 was described as 'negative' and a TMPRSS2-ERG score ≥35 as 'positive.'

Analysis based on number (N) of patients with a valid value. ITT population.

End point type	Secondary

End point timeframe:

At baseline, month 1, 3 and 6 post-treatment

End point values	Triptorelin (Decapeptyl®) 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	322			
Units: Number of subjects				
Baseline: Non-assessable (N=322)	33			
Baseline: <35 negative (N=322)	140			
Baseline: ≥35 positive (N=322)	149			
Month 1: Non-assessable (N=322)	117			
Month 1: <35 negative (N=322)	97			
Month 1: ≥35 positive (N=322)	106			
Month 1: Missing-No sample analysis done (N=322)	2			
Month 3: Non-assessable (N=313)	213			
Month 3: <35 negative (N=313)	45			
Month 3: ≥35 positive (N=313)	53			
Month 3: Missing-No sample analysis done (N=313)	2			
Month 6: Non-assessable (N=298)	241			
Month 6: <35 negative (N=298)	24			
Month 6: ≥35 positive (N=298)	27			
Month 6: Missing-No sample analysis done (N=298)	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients Medically Castrated (i.e. With Serum Testosterone Levels of <50 ng/dL)

End point title	Proportion of Patients Medically Castrated (i.e. With Serum Testosterone Levels of <50 ng/dL)
End point description:	
Analysis based on number (N) of patients with a valid value. ITT population.	
End point type	Secondary
End point timeframe:	
At month 1, 3 and 6 post-treatment	

End point values	Triptorelin (Decapeptyl®) 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	322			
Units: Percentage of participants				
number (not applicable)				
Month 1 (N=322)	94.7			
Month 3 (N=313)	95.2			
Month 6 (N=298)	90.9			

Statistical analyses

No statistical analyses for this end point

Secondary: PSA Level

End point title	PSA Level

End point description:

Analysis based on number (N) of patients with a valid value. ITT population.

End point type	Secondary

End point timeframe:

At baseline, month 1, 3 and 6 post-treatment

End point values	Triptorelin (Decapeptyl®) 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	322			
Units: µg/L				
median (full range (min-max))				
Baseline (N=321)	45.4 (1 to 12239)			
Month 1 (N=320)	8.3 (0 to 581)			
Month 3 (N=311)	1.8 (0 to 969)			
Month 6 (N=296)	1.2 (0 to 1251)			

Statistical analyses

No statistical analyses for this end point

Secondary: Safety, Assessed Through the Collection of Adverse Events (AEs)

End point title	Safety, Assessed Through the Collection of Adverse Events (AEs)

End point description:

End point type	Secondary

End point timeframe:

For the duration of the study (up to month 6)

End point values	Triptorelin (Decapeptyl®) 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	325			
Units: Number of subjects				
Any Adverse Events (AEs)	193			
Any Treatment Emergent Adverse Events (TEAEs)	190			
TEAEs Leading to Withdrawal	11			
TEAEs Leading to Death	11			
Serious Adverse Events (SAEs)	37			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to month 6	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.1

Reporting groups	
Reporting group title	Triptorelin (Decapeptyl®) 22.5 mg

Reporting group description:

Triptorelin (Decapeptyl®): One intramuscular injection of triptorelin (Decapeptyl®) 22.5 mg performed once all baseline procedures and assessments have been completed.

Serious adverse events	Triptorelin (Decapeptyl®) 22.5 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	37 / 325 (11.38%)		
number of deaths (all causes)	11		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone pain due to metastasis			
subjects affected / exposed	2 / 325 (0.62%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Rectum tumor			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Larynx adenocarcinoma			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cancer progression			

subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Urothelial tumor in the bladder				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Right central pulmonary tumor malignant				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Claudication				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blocked nephrostomy catheter				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Septic venous thrombophlebitis				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fever				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Sudden death			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Unspecific thoracic pain			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic pain			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Allergy to conc med			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Hemorrhage prostate			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bilateral pleural effusion			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Right pleurisy			

subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Depression				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Suicide				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Investigations				
Weight gain				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Deliberate medication overdose				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				

subjects affected / exposed	2 / 325 (0.62%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardio respiratory arrest			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Atrial fibrillation			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heart failure			
subjects affected / exposed	3 / 325 (0.92%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Chronic heart failure			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Paraplegia			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			

Severe anemia				
subjects affected / exposed	2 / 325 (0.62%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Diarrhoea				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fecal peritonitis				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Entero-cutaneous fistula				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perforated colon				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perforated gall bladder				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Right inguinal hernia				
subjects affected / exposed	1 / 325 (0.31%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subileus				

subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Liver failure			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Heamaturia			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute renal failure			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
End stage renal failure			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	4 / 325 (1.23%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urethral stricture			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue			

disorders			
Increased pain in right thigh			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Worsening of chronic lumbago			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Chest infection			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis acute			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute pneumonia			
subjects affected / exposed	2 / 325 (0.62%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Pneumonia pneumocystis			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septicaemia			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Urosepsis			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septicemia due to catheter			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypocalcemia			
subjects affected / exposed	1 / 325 (0.31%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Triptorelin (Decapeptyl®) 22.5 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	89 / 325 (27.38%)		
Vascular disorders			
Hot flush			
subjects affected / exposed	89 / 325 (27.38%)		
occurrences (all)	89		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported