Clinical trial results:
A phase IV, randomised, open-label, multi-centre study to assess the impact on disease control, safety, patient and clinician experience of changing patients with advanced prostate cancer from a 3-monthly LHRH agonist to 6-monthly injections of Decapeptyl® SR 22.5 mg

Summary

EudraCT number	2011-004213-16
Trial protocol	GB
Global end of trial date	06 February 2014

Results information

Result version number	v2 (current)
This version publication date	29 May 2025
First version publication date	25 July 2015
Version creation reason	• Correction of full data set Data validation only

Trial information

Trial identification

Sponsor protocol code	A-97-52014-181

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01673984
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen Limited
Sponsor organisation address	190 Bath Road, Slough, Berkshire, United Kingdom, SL1 3XE
Public contact	Medical Director, Uro-Oncology, Ipsen Limited, clinical.trials@ipsen.com
Scientific contact	Medical Director, Uro-Oncology, Ipsen Limited, 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	17 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 February 2014
Global end of trial reached?	Yes
Global end of trial date	06 February 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To demonstrate non-inferiority of Decapeptyl® SR 22.5 mg compared with a standard 3-monthly LHRH agonist in maintaining biochemical castration (STT level ≤0.5 ng/mL, changed to STT level <0.5 ng/mL to be in accordance with the European Association of Urology [EAU] Guideline) after 6 months of treatment.

Protection of trial subjects:

The study and the archiving of essential documents were performed in compliance with Good Clinical Practices (GCP) and in accordance with the Declaration of Helsinki. The currently preferred such agents are LHRH agonists such as triptorelin (Decapeptyl® Sustained Released [SR]), which have an established and favourable benefit-risk profile, are convenient and many practitioners like the reversibility of the treatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 August 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
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)	1
From 65 to 84 years	18

85 years and over	2

Subject disposition

Recruitment

Recruitment details:

35 subjects screened and 27 subjects were enrolled. Following enrollment, 21 patients were randomised before the study was prematurely discontinued.

Pre-assignment

Screening details:

[Not Specified]

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Decapeptyl® SR 22.5 mg

Arm description:

Decapeptyl® SR 22.5mg: 22.5mg, intramuscular injection, given on day 1 / month 0 & month 6 (+/- 7 days).

Arm type	Experimental
Investigational medicinal product name	Decapeptyl® SR
Investigational medicinal product code	
Other name	Triptorelin pamoate
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Decapeptyl® SR 22.5mg: 22.5mg, intramuscular injection, given on day 1 / month 0 & month 6 (+/- 7 days).

Arm title	Current 3-monthly LHRH Agonist

Arm description:

One of the following: Decapeptyl® SR 11.25mg, Prostap® 3 DCS 11.25mg, Zoladex® LA 10.8mg

Decapeptyl® SR 11.25mg; Prostap® 3 DCS 11.25mg; Zoladex® LA 10.8mg: For Decapeptyl® SR 11.25mg: 11.25 mg, intramuscular injection For Prostap® 3 DCS 11.25mg: 11.25mg, depot injected subcutaneously For Zoladex® LA 10.8mg: 10.8mg, depot injected subcutaneously into anterior abdominal wall.

Arm type	Active comparator
Investigational medicinal product name	Decapeptyl SR® 11.25 mg
Investigational medicinal product code	
Other name	Triptorelin pamoate
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One of the following: Decapeptyl® SR 11.25mg, Prostap® 3 DCS 11.25mg, Zoladex® LA 10.8mg

Decapeptyl® SR 11.25mg; Prostap® 3 DCS 11.25mg; Zoladex® LA 10.8mg: For Decapeptyl® SR 11.25mg: 11.25 mg, intramuscular injection For Prostap® 3 DCS 11.25mg: 11.25mg, depot injected subcutaneously For Zoladex® LA 10.8mg: 10.8mg, depot injected subcutaneously into anterior abdominal wall.

Number of subjects in period 1	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist
Started	14	7
Completed	4	1
Not completed	10	6
Study termination	9	6
Adverse event, non-fatal	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Decapeptyl® SR 22.5 mg
Reporting group description:	
Decapeptyl® SR 22.5mg: 22.5mg, intramuscular injection, given on day 1 / month 0 & month 6 (+/- 7 days).	
Reporting group title	Current 3-monthly LHRH Agonist
Reporting group description:	
One of the following: Decapeptyl® SR 11.25mg, Prostap® 3 DCS 11.25mg, Zoladex® LA 10.8mg Decapeptyl® SR 11.25mg; Prostap® 3 DCS 11.25mg; Zoladex® LA 10.8mg: For Decapeptyl® SR 11.25mg: 11.25 mg, intramuscular injection For Prostap® 3 DCS 11.25mg: 11.25mg, depot injected subcutaneously For Zoladex® LA 10.8mg: 10.8mg, depot injected subcutaneously into anterior abdominal wall.	

Reporting group values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist	Total
Number of subjects	14	7	21
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	77.2	78.7	
standard deviation	± 5.4	± 9.3	-
Gender categorical Units: Subjects			
Male	14	7	21
Employment status/Occupation Units: Subjects			
Employed	2	1	3
Retired	12	6	18

End points

End points reporting groups

Reporting group title	Decapeptyl® SR 22.5 mg
Reporting group description:	
Decapeptyl® SR 22.5mg: 22.5mg, intramuscular injection, given on day 1 / month 0 & month 6 (+/- 7 days).	
Reporting group title	Current 3-monthly LHRH Agonist
Reporting group description:	
One of the following: Decapeptyl® SR 11.25mg, Prostap® 3 DCS 11.25mg, Zoladex® LA 10.8mg Decapeptyl® SR 11.25mg; Prostap® 3 DCS 11.25mg; Zoladex® LA 10.8mg: For Decapeptyl® SR 11.25mg: 11.25 mg, intramuscular injection For Prostap® 3 DCS 11.25mg: 11.25mg, depot injected subcutaneously For Zoladex® LA 10.8mg: 10.8mg, depot injected subcutaneously into anterior abdominal wall.	

Primary: Percentage of Participants Maintaining Biochemical Castration

End point title	Percentage of Participants Maintaining Biochemical Castration[1]
End point description:	
Patients with serum total testosterone (STT) level lower than 0.5 ng/mL after 6 months of treatment. Analysis based on intent-to-treat (ITT) population comprised of 21 patients.	
End point type	Primary
End point timeframe:	
6 months	

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: As the endpoint is descriptive in nature, no statistical analysis was presented.

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	7		
Units: Percentage of participants				
number (not applicable)	92.9	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Maintaining Biochemical Castration After 12 Months of Treatment

End point title	Percentage of Participants Maintaining Biochemical Castration After 12 Months of Treatment
End point description:	
Patients with serum total testosterone (STT) level lower than 0.5 ng/mL, 12 months after randomisation. Analysis based on the number of subjects with a valid value in the ITT population comprised of 21 patients.	
End point type	Secondary

End point timeframe:

12 months

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: Percentage of participants				
number (not applicable)	22.2	25		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Demonstrating Stable Prostate-specific Antigen (PSA) Levels

End point title	Percentage of Participants Demonstrating Stable Prostate-specific Antigen (PSA) Levels

End point description:

Stable PSA level was noted as value either lower or less than 25% higher than the baseline value, or PSA value ≤0.5 ng/mL higher than the baseline value, if value ≥25% higher than the baseline value. Analysis based on number (n) of patients with a valid value in the intent-to-treat (ITT) population which comprised of 21 patients.

End point type	Secondary

End point timeframe:

6 and 12 months

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	7		
Units: Percentage of participants				
number (not applicable)				
6 months (n = 13, 7)	84.6	100		
12 months (n = 2, 1)	50	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Life Using EuroQol 5 Dimensions 5 Levels [EQ-5D-5L] Questionnaire

End point title	Change From Baseline in Quality of Life Using EuroQol 5 Dimensions 5 Levels [EQ-5D-5L] Questionnaire

End point description:

The EQ-5D-5L questionnaire consisted of a description of raw data which comprised of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension had five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The visual analogical scale of the EQ-5D-5L questionnaire was numbered from 0 to 100 (0 meaning the worst health the patient can imagine and 100 the best health the patient can imagine). Analysis based on the number of subjects with a valid value in the ITT population which comprised of 21 patients.

End point type	Secondary

End point timeframe:

Baseline and Month 12

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: Units on a scale				
arithmetic mean (confidence interval 95%)	71.7 (40.4 to 102.9)	70.0 (-57.1 to 197.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient Satisfaction With Medication Using Treatment Satisfaction Questionnaire for Medication (TSQM Version II)

End point title	Change From Baseline in Patient Satisfaction With Medication Using Treatment Satisfaction Questionnaire for Medication (TSQM Version II)

End point description:

TSQM comprised of four dimensions: effectiveness, side effects, convenience and overall global satisfaction. Each score ranged from 0 to 100. For effectiveness, convenience and overall global satisfaction scores, 0 indicated an extreme dissatisfaction and 100 indicated an extreme satisfaction. For side effects score, 0 indicated an extreme dissatisfaction and 100 indicated no dissatisfaction at all. Analysis based on the number (n) of subjects with a valid value in each arm of the ITT population which comprised of 21 patients.

End point type	Secondary

End point timeframe:

6 and 12 month

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	7		
Units: units on a scale				
arithmetic mean (confidence interval				

95%)				
Baseline to 6 months - Effectiveness (n= 13, 7)	3.2 (-12.5 to 18.9)	13.1 (-10.8 to 37.0)		
Baseline to 12 months - Effectiveness (n= 3, 2)	-33.3 (-74.7 to 8.1)	-12.5 (-383.1 to 358.1)		
Baseline to 6 months - Side Effects (n= 13, 7)	-2.6 (-12.9 to 7.8)	4.8 (-6.0 to 15.5)		
Baseline to 12 months - Side Effects (n= 3, 2)	-25.0 (-115.2 to 65.2)	12.5 (-146.3 to 171.3)		
Baseline to 6 months - Convenience (n= 13, 7)	4.7 (-6.3 to 15.7)	2.0 (-9.8 to 13.7)		
Baseline to 12 months - Convenience (n= 3, 2)	-1.9 (-36.6 to 32.9)	2.8 (-103.1 to 108.7)		
Baseline to 6months -Global Satisfaction(n= 12, 6)	-0.7 (-15.9 to 14.5)	-4.2 (-11.5 to 3.2)		
Baseline to 12months -Global Satisfaction(n= 2, 2)	-12.5 (-171.3 to 146.3)	4.2 (-48.8 to 57.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Satisfaction With Treatment

End point title	Patient Satisfaction With Treatment

End point description:

Using a non-validated study-specific descriptive Likert-type scale (with no units) comprising a simple six-question patient questionnaire. No participant analysis as no data was collected due to low number of participants recruited in the study.

End point type	Secondary

End point timeframe:

Month 12

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: Units on a scale				
arithmetic mean (standard deviation)	()	()		

Notes:

[2] - No data was collected due to low number of participants recruited in the study.

[3] - No data was collected due to low number of participants recruited in the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Changed Injection Frequency After Completion of the Study

End point title	Percentage of Participants who Changed Injection Frequency

	After Completion of the Study

End point description:

Analysis based on the number of subjects with a valid value in the ITT population which comprised of 21 patients.

End point type	Secondary

End point timeframe:

Month 12

End point values	Decapeptyl® SR 22.5 mg	Current 3-monthly LHRH Agonist		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: percentage of participants				
number (not applicable)	80	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 12 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups	
Reporting group title	Decapeptyl® SR 22.5mg
Reporting group description:	
Decapeptyl® SR 22.5mg: 22.5mg, intramuscular injection, given on day 1 / month 0 & month 6 (+/- 7 days).	
Reporting group title	Current 3-monthly LHRH Agonist
Reporting group description:	
One of the following: Decapeptyl® SR 11.25mg, Prostap® 3 DCS 11.25mg, Zoladex® LA 10.8mg Decapeptyl® SR 11.25mg; Prostap® 3 DCS 11.25mg; Zoladex® LA 10.8mg: For Decapeptyl® SR 11.25mg: 11.25 mg, intramuscular injection For Prostap® 3 DCS 11.25mg: 11.25mg, depot injected subcutaneously For Zoladex® LA 10.8mg: 10.8mg, depot injected subcutaneously into anterior abdominal wall.	

Serious adverse events	Decapeptyl® SR 22.5mg	Current 3-monthly LHRH Agonist	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Decapeptyl® SR 22.5mg	Current 3-monthly LHRH Agonist	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 14 (85.71%)	7 / 7 (100.00%)	
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Hot flush			
subjects affected / exposed	1 / 14 (7.14%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Peripheral vascular disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Gait disturbance			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Oedema peripheral			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Suprapubic pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	

Reproductive system and breast disorders			
Penile pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Prostatitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Cough			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Dyspnoea			
subjects affected / exposed	3 / 14 (21.43%)	0 / 7 (0.00%)	
occurrences (all)	3	0	
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Investigations			
Haemoglobin decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Serum ferritin increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

Humerus fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Joint injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Laceration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Cardiac disorders			
Bundle branch block right			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	5 / 14 (35.71%)	0 / 7 (0.00%)	
occurrences (all)	5	0	
Headache			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Hemiparesis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Poor quality sleep			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Transient ischaemic attack			

subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Deafness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Tinnitus			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Eye disorders			
Cataract			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Conjunctival haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Colitis microscopic			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Eructation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Glossodynia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Hiatus hernia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Oesophagitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Hyperhidrosis			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Rash			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Skin ulcer			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Micturition urgency			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pollakiuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	3 / 14 (21.43%)	1 / 7 (14.29%)	
occurrences (all)	3	1	
Muscle atrophy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Ear infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Eye infection bacterial			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Lower respiratory tract infection			
subjects affected / exposed	3 / 14 (21.43%)	1 / 7 (14.29%)	
occurrences (all)	3	1	
Upper respiratory tract infection			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Viral infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Lobar pneumonia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Gout			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Hypercholesterolaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	

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