Clinical trial results:
A multicentre, prospective, single arm, open-label 96 week observational trial of the tolerability, adherence and efficacy of a dolutegravir/abacavir/lamivudine single tablet regimen in HIV-1 antibody positive people living with HIV with a history of injection drug use switching from existing ART or starting treatment after discontinuation of ART

Summary

EudraCT number	2016-000087-42
Trial protocol	IE ES
Global end of trial date	06 September 2021

Results information

Result version number	v1 (current)
This version publication date	22 May 2025
First version publication date	22 May 2025

Trial information

Trial identification

Sponsor protocol code	TAISTR 16

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02659761
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University College Dublin
Sponsor organisation address	Belfield, Dublin, Ireland, Dublin 4
Public contact	Centre for Experimental Pathogen Host Research , University College Dublin, cephr@ucd.ie
Scientific contact	Centre for Experimental Pathogen Host Research , University College Dublin, cephr@ucd.ie

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	11 December 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 September 2021
Global end of trial reached?	Yes
Global end of trial date	06 September 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the tolerability, adherence and efficacy of single tablet dolutegravir/abacavir/lamivudine antiretroviral therapy in people living with HIV with a history of injection drug use (current/recent IDU) switching from existing ART or starting treatment after discontinuation of ART

Protection of trial subjects:

This trial was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines. All subjects provided written informed consent before undergoing any trial related procedures. The trial was reviewed and approved by the Competent Authorities and the local Research Ethics Committees (REC).

An independent Data and Safety Monitoring Board (DSMB) was established to monitor all aspects of the trial. The DSMB consideres findings from any other relevant studies and reviews trial data on recruitment, safety, and adherence to trial strategies and efficacy in strict confidence approximately every 6 months.

Subjects attended a total of 11 clinic visits over 96 weeks of the study. All visits included medical/clinical review including assessments of safety and records of adverse events. For women of childbearing potential, pregnancy tests were performed at the screening visit (urinary βHCG lateral flow) and subsequently during the study visits. If a subject was found to be pregnant, they were discontinued from the study and the outcome of the pregnancy test recorded in the study CRF.

Female subjects were instructed to notify the investigator if they became pregnant at any time during the study, or if they became pregnant within 30 days of last study drug dose. Subjects who became pregnant or who suspected that they were pregnant during the study had to report the information to the investigator and discontinue study drug immediately. The investigator would counsel all patients on the protocol-specified methods for avoiding pregnancy during the study.
All men subjects were educated in using a barrier contraception method in order to reduce the risk of viral transmission to their partners.

Background therapy:

At enrolment subjects are allocated to receive a once-daily, fixed-dose combination (FDC) single-tablet regimen (STR) containing the integrase strand transfer inhibitor (INSTI) dolutegravir (DTG) 50 mg with the nucleoside reverse transcriptase inhibitors (NRTIs) abacavir sulfate (abacavir, ABC) 600 mg and lamivudine (3TC) 300 mg.

Evidence for comparator:

N/A

Actual start date of recruitment	01 March 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Ireland: 33
Worldwide total number of subjects	33
EEA total number of subjects	33

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)	33
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started in Ireland in March 2016. Of 45 recruited, 8 were screen failure, 4 were lost after screening and 33 subjects contributed to the analyses (ITT population). The first participant was recruited on 27/02/2017 and the last on 01/03/2019.

Pre-assignment

Screening details:

Study population will comprised HIV-1 positive, adult, people living with HIV (PLWH) with a history of injecting drug use (IDU) who were either ART-naïve or switched from existing ART or started treatment after discontinuation of ART. (IDU as HIV acquisition risk or current or recent (past 12 months) history of IDU)

Period 1

Period 1 title	Final Analysis (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Arm title	Treatment arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ABC/3TC/DTG
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

The study treatments consist of Triumeq- a film-coated once-daily fixed-dose combination (FDC) single-tablet regimen (STR) that contains 50 mg of the integrase inhibitor (INI) dolutegravir (DTG), 600 mg of the nucleoside reverse transcriptase inhibitor (NRTIs) abacavir sulfate (abacavir, ABC) and 300 mg of the NRTI lamivudine (3TC).
The recommended dose of Triumeq is one tablet (600 mg abacavir, 50 mg dolutegravir and 300 mg lamivudine), taken orally, once daily. Directions for dosage timing, food requirements and special precautions will be provided by clinic doctor or pharmacist as part of routine care to ensure the appropriate intake of the IMP.

Number of subjects in period 1	Treatment arm
Started	33
Completed	24
Not completed	9
Adverse event, serious fatal	1
Consent withdrawn by subject	2
Unknown	1
Lost to follow-up	5

Baseline characteristics

Reporting groups

Reporting group title	Final Analysis (overall period)

Reporting group description: -

Reporting group values	Final Analysis (overall period)	Total	
Number of subjects	33	33	
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)	33	33	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	43		
inter-quartile range (Q1-Q3)	40 to 47	-	
Gender categorical Units: Subjects			
Female	9	9	
Male	24	24	
Ethnicity Units: Subjects			
Caucasian	33	33	
HIV transmission risk group Units: Subjects			
Injecting drug use	21	21	
Heterosexual contact	6	6	
Needle stick injury	2	2	
Victim of sexul assualt	2	2	
Unknown	2	2	
Employment status Units: Subjects			
Unemployed	21	21	
Employed	2	2	
Unknown	3	3	
Missing	7	7	
Highest educational grade achieved Units: Subjects			
Primary	9	9	
Secondary	23	23	

Missing	1	1	
Housing status Units: Subjects			
Stable accommodation	22	22	
Temporary accommodation	8	8	
Homeless	3	3	
Smoking status Units: Subjects			
Current Smoker	28	28	
Non-smoker	3	3	
Missing	2	2	
ART status Units: Subjects			
ART-experienced	31	31	
ART-naive	2	2	
PI-based ART Units: Subjects			
Yes	30	30	
No	3	3	
Undetectable HIV RNA copies/ml Units: Subjects			
>200 cps/ml	12	12	
<200 cps/ml	20	20	
Missing	1	1	
Baseline CD4+ T-cells Units: cells/mm^3			
median	541.5		
inter-quartile range (Q1-Q3)	377.0 to 774.0	-	
Baseline CD8+ T-cells Units: cells/mm^3			
median	916.0		
inter-quartile range (Q1-Q3)	606.0 to 1049.0	-	
Baseline BMI Units: kg/m^2			
median	21.3		
inter-quartile range (Q1-Q3)	18.6 to 24.1	-	
Length of HIV diagnosis Units: years			
median	10.0		
inter-quartile range (Q1-Q3)	4.0 to 13.0	-	

End points

End points reporting groups

Reporting group title	Treatment arm
Reporting group description: -	
Subject analysis set title	Treatment arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Enrolled subjects	

Primary: Efficacy - Percentage of subjects with HIV-VL <=40 copies/mL at week 48

End point title	Efficacy - Percentage of subjects with HIV-VL <=40 copies/mL at week 48
End point description:	
For the analysis of efficacy, virological suppression was defined as HIV-RNA <40 copies/mL. The percentage of subjects with virological suppression at each visit was summarised using descriptive statistics (n and %).	
End point type	Primary
End point timeframe:	
From baseline to week 48	

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20[1]	20		
Units: subjects				
<=40 copies/ml	15	15		
>40 copies/ml	5	5		

Notes:

[1] - Of 33 subjects, 20 had follow up data on this endpoint

Statistical analyses

Statistical analysis title	Percentage of subjects with HIV-VL <=40 copies/mL
Statistical analysis description:	
Percentage is based on subject with measurements at each visit. Confidence interval are based on Clopper-Pearson	
Comparison groups	Treatment arm v Treatment arm
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Proportion
Point estimate	75
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.9
upper limit	91.3

Primary: Tolerability - Self Reported adverse effects over 96 weeks

End point title	Tolerability - Self Reported adverse effects over 96 weeks[2]

End point description:

Tolerability through self-reported adverse effects and directed symptom questionnaire. Proportions will be used to quantify the occurrence of self-reported adverse effects.

End point type	Primary

End point timeframe:

From baseline to week 96

Notes:

[2] - 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: Descriptive analysis only was planned for this endpoint

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	33[3]	33[4]		
Units: number of subjects	27	27		

Notes:

[3] - Of 33 enrolled subjects, 27 had available data on this endpoint

[4] - Of 33 enrolled subjects, 27 had available data on this endpoint

Statistical analyses

No statistical analyses for this end point

Primary: Adherence - Percentage of subject with unscheduled ART interruptions over 96 weeks

End point title	Adherence - Percentage of subject with unscheduled ART interruptions over 96 weeks[5]

End point description:

Percentage of subject with unscheduled ART discontinuations/interruptions over 96 weeks.
The percentage of subjects is summarised using descriptive statistics (n and %).

End point type	Primary

End point timeframe:

From baseline to week 96

Notes:

[5] - 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: Descriptive analysis only was planned for this endpoint

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	33[6]	33[7]		
Units: subjects	20	20		

Notes:

[6] - Of 33 enrolled subjects, 20 had data on this endpoint

[7] - Of 33 enrolled subjects, 20 had data on this endpoint

Statistical analyses

No statistical analyses for this end point

Primary: Adherence - Change of Medication possession ratio (MPR) at 48 weeks

End point title	Adherence - Change of Medication possession ratio (MPR) at 48 weeks

End point description:

MPR is a widely used measure of adherence based on pharmacy accounts, and it measures the proportion of days since ART initiation that a patient is in possession of medications.
MPR at each visit was calculated as the total treatment days of supply(prescription fills) divided by the days of follow-up from baseline (treatment started)
MPR ≥0.8 considered adequate adherence.

End point type	Primary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	22[8]	22[9]		
Units: ratio				
arithmetic mean (standard deviation)	0.84 (± 0.246)	0.84 (± 0.246)		

Notes:

[8] - Of 33 subjects, 22 had follow up data on this endpoint

[9] - Of 33 subjects, 22 had follow up data on this endpoint

Statistical analyses

Statistical analysis title	Change in MPR at week 48
Comparison groups	Treatment arm v Treatment arm
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other[10]
Parameter estimate	Mean difference (final values)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.93
Variability estimate	Standard deviation
Dispersion value	0.246

Notes:

[10] - MPR was calculated at each study visit as mean and standard deviation (SD).
Confidence interval are based on one sample t-test formula

Secondary: Percentage of subjects with HIV-VL <=40 copies/mL at week 96

End point title	Percentage of subjects with HIV-VL <=40 copies/mL at week 96

End point description:

For the analysis of efficacy, virological suppression was defined as HIV-RNA <40 copies/mL.

The percentage of subjects with virological suppression at each visit was summarised using descriptive statistics (n and %).

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	22[11]	22[12]		
Units: subjects				
<=40 copies/ml	18	18		
>40 copies/ml	4	4		

Notes:

[11] - Of 33 enrolled subjects, 22 had data on this endpoint

[12] - Of 33 enrolled subjects, 22 had data on this endpoint

Statistical analyses

Statistical analysis title	Percentage of subjects with HIV-VL <=40 copies/mL

Statistical analysis description:

Percentage is based on subject with measurements at each visit.
Confidence interval are based on Clopper-Pearson

Comparison groups	Treatment arm v Treatment arm
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Proportion
Point estimate	81.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.7
upper limit	94.8

Secondary: Change of Medication possession ratio (MPR) at 96 weeks

End point title	Change of Medication possession ratio (MPR) at 96 weeks

End point description:

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	24	24		
Units: ratio				
arithmetic mean (standard deviation)	0.75 (± 0.308)	0.75 (± 0.308)		

Statistical analyses

Statistical analysis title	Change in MPR at week 96
Comparison groups	Treatment arm v Treatment arm
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.85
Variability estimate	Standard deviation
Dispersion value	0.308

Secondary: Change in CD4+ T-cell counts over 96 weeks

End point title	Change in CD4+ T-cell counts over 96 weeks
End point description:	
Change from baseline on CD4+ T-cell counts for the analysis of efficacy	
End point type	Secondary
End point timeframe:	
From baseline to week 96	

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19[13]	19[14]		
Units: cells/mm3				
median (inter-quartile range (Q1-Q3))	-4.0 (-148.0 to 214.0)	-4.0 (-148.0 to 214.0)		

Notes:

[13] - Of 33 subjects enrolled, 19 had follow-up data available on this endpoint

[14] - Of 33 subjects enrolled, 19 had follow-up data available on this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Estimated number of weeks of missed ART over 96 weeks of follow-up

End point title	Estimated number of weeks of missed ART over 96 weeks of follow-up

End point description:

Median duration of ART interruption/discontinuation in weeks.
Excludes subject who discontinued IMP completely (and switched to other ART) but remained in the study

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	28	28		
Units: weeks				
median (inter-quartile range (Q1-Q3))	12.3 (4.9 to 33.2)	12.3 (4.9 to 33.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in BMD LS over 96 weeks

End point title	Change in BMD LS over 96 weeks

End point description:

Bone mineral density (BMD) was determined by dual energy X-ray Absorptiometry (DXA).
Whole body and regional DXA scan for BMD were measured at baseline and 24, 48 and 96 weeks.
Change in BMD at the Lumbar spine (LS) is expressed as median (IQR)

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16[15]	16[16]		
Units: g/cm2				
median (inter-quartile range (Q1-Q3))	0.030 (-0.001 to 0.055)	0.030 (-0.001 to 0.055)		

Notes:

[15] - Of 33 subjects enrolled, 16 had value available on this endpoint

[16] - Of 33 subjects enrolled, 16 had value available on this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Change in BMD FN over 96 weeks

End point title	Change in BMD FN over 96 weeks

End point description:

Bone mineral density (BMD) was determined by dual energy X-ray Absorptiometry (DXA).
Whole body and regional DXA scan for BMD were measured at baseline and 24, 48 and 96 weeks.
Change in BMD at the Femoral Neck (FN) is expressed as median (IQR)

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19	19		
Units: g/cm2				
median (inter-quartile range (Q1-Q3))	0.005 (-0.035 to 0.033)	0.005 (-0.035 to 0.033)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in BMD TH over 96 weeks

End point title	Change in BMD TH over 96 weeks

End point description:

Bone mineral density (BMD) was determined by dual energy X-ray Absorptiometry (DXA).
Whole body and regional DXA scan for BMD were measured at baseline and 24, 48 and 96 weeks.
Change in BMD at the Total Hip (TH) is expressed as median (IQR)

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19	19		
Units: g/cm2				
median (inter-quartile range (Q1-Q3))	0.023 (-0.020 to 0.031)	0.023 (-0.020 to 0.031)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Emotional well-being domain at week 48

End point title	Change in HRQOL - Emotional well-being domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

Baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	13	13		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-12.0 to 4.0)	0.0 (-12.0 to 4.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Energy/fatigue domain at week 48

End point title	Change in HRQOL - Energy/fatigue domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

Baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	13	13		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-15.0 to 5.0)	0.0 (-15.0 to 5.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - General Health domain at week 48

End point title	Change in HRQOL - General Health domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	16		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	-10.0 (-27.5 to -2.5)	-10.0 (-27.5 to -2.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Pain domain at week 48

End point title	Change in HRQOL - Pain domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	16		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	-5.0 (-38.8 to 11.3)	-5.0 (-38.8 to 11.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Physical functioning domain at week 48

End point title	Change in HRQOL - Physical functioning domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	16		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	2.5 (0.0 to 32.5)	2.5 (0.0 to 32.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Role functioning/emotional domain at week 48

End point title	Change in HRQOL - Role functioning/emotional domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data

collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	14	14		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-33.3 to 0.0)	0.0 (-33.3 to 0.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Role functioning/physical domain at week 48

End point title	Change in HRQOL - Role functioning/physical domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	16		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (0.0 to 37.5)	0.0 (0.0 to 37.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Social functioning domain at week 48

End point title	Change in HRQOL - Social functioning domain at week 48

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 48

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	14	14		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-25.0 to 0.0)	0.0 (-25.0 to 0.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Emotional well-being Domain at week 96

End point title	Change in HRQOL - Emotional well-being Domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19	19		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-12.0 to 4.0)	0.0 (-12.0 to 4.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Energy/fatigue domain at week 96

End point title	Change in HRQOL - Energy/fatigue domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19	19		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	-5.0 (-20.0 to 15.0)	-5.0 (-20.0 to 15.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - General Health domain at week 96

End point title	Change in HRQOL - General Health domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	21	21		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	-5.0 (-20.0 to 5.0)	-5.0 (-20.0 to 5.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Pain domain at week 96

End point title	Change in HRQOL - Pain domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	21	21		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	-7.5 (-22.5 to 10.0)	-7.5 (-22.5 to 10.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Physical functioning domain at week 96

End point title	Change in HRQOL - Physical functioning domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role

functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	5.0 (-2.5 to 21.1)	5.0 (-2.5 to 21.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Role functioning/emotional domain at week 96

End point title	Change in HRQOL - Role functioning/emotional domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18	18		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-33.3 to 0.0)	0.0 (-33.3 to 0.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HRQOL - Role functioning/physical domain at week 96

End point title	Change in HRQOL - Role functioning/physical domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	21	21		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Chnage in HRQOL - Social Functioning domain at week 96

End point title	Chnage in HRQOL - Social Functioning domain at week 96

End point description:

Health Related Quality of Life (HRQOL) was estimated using the SF-36 health survey items with data collected at baseline, week 48 and week 96.
Responses were summarized into common sub-domains of the measures including emotional wellbeing, energy/fatigue, general health, pain, physical functioning, role functioning/emotional, role functioning/physical and social functioning.
Each subdomain was scored from 0-100, with higher scores indicating better health.

End point type	Secondary

End point timeframe:

From baseline to week 96

End point values	Treatment arm	Treatment arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19	19		
Units: score 0 to 100				
median (inter-quartile range (Q1-Q3))	0.0 (-12.5 to 12.5)	0.0 (-12.5 to 12.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Signing of Informed Consent through End of Study (Up to 96 weeks)

Adverse event reporting additional description:

Data from all subjects entering the study will be included in the analysis of safety.
Adverse event (AE) term recorded during the study will be mapped to a system organ class and preferred term

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21

Reporting groups

Reporting group title	Safety population

Reporting group description:

Data from all subjects entering the study will be included in the analysis of safety. The number of adverse events (AEs) and serious adverse events (SAEs) will be tabulated by severity and treatment received

Serious adverse events	Safety population		
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 33 (39.39%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Upper limb fracture			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Lower limb fracture				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple fractures				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin laceration				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep vein thrombosis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Seizure				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				

subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Intentional self-injury			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Mental status changes			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Lower respiratory tract infection bacterial			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Groin abcess			

subjects affected / exposed	2 / 33 (6.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial pyelonephritis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal candidiasis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic inflammatory disease			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular graft infection			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	1 / 33 (3.03%)		
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	Safety population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 33 (93.94%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Skin papilloma			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	2		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Injury associated with device			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	5 / 33 (15.15%)		
occurrences (all)	5		
Cough			

subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Bronchial secretion retention			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Pharyngeal ulceration			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	5 / 33 (15.15%)		
occurrences (all)	5		
Insomnia			
subjects affected / exposed	5 / 33 (15.15%)		
occurrences (all)	5		
Anxiety			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Mental status changes			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Acute psychosis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Intentional self-injury			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Alcoholism			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Mood swings			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		

Panic attack subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Investigations Weight increased subjects affected / exposed occurrences (all)	3 / 33 (9.09%) 3		
Alanine aminotransferase increase subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2		
C-reactive protein increased subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Helicobacter test positive subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Liver function test increased subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2		
Upper limb fracture subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2		
Alcohol poisoning subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Fall subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Head injury subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Lower limb fracture			

subjects affected / exposed occurrences (all) Multiple fractures subjects affected / exposed occurrences (all) Skin laceration subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1 1 / 33 (3.03%) 1 1 / 33 (3.03%) 1		
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	 1 / 33 (3.03%) 1		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Neuropathy peripheral subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all) Restless legs syndrome subjects affected / exposed occurrences (all) Seizure subjects affected / exposed occurrences (all) Seizure like phenomena subjects affected / exposed occurrences (all)	 10 / 33 (30.30%) 10 2 / 33 (6.06%) 2 2 / 33 (6.06%) 2 1 / 33 (3.03%) 1 1 / 33 (3.03%) 1 1 / 33 (3.03%) 2 1 / 33 (3.03%) 1		
Blood and lymphatic system disorders			

Thrombocytopenia subjects affected / exposed occurrences (all)	10 / 33 (30.30%) 10			
Anaemia subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 5			
Anaemia folate deficiency subjects affected / exposed occurrences (all)	4 / 33 (12.12%) 4			
Neutropenia subjects affected / exposed occurrences (all)	3 / 33 (9.09%) 3			
Leukocytosis subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2			
Leukopenia subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1			
Pancytopenia subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1			
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	8 / 33 (24.24%) 10			
Diarrhoea subjects affected / exposed occurrences (all)	6 / 33 (18.18%) 6			
Abdominal pain subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 5			
Vomiting subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 5			
Constipation				

subjects affected / exposed	4 / 33 (12.12%)			
occurrences (all)	4			
Flatulence				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Gastritis erosive				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Abdominal discomfort				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Abdominal pain lower				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Barrett's oesophagus				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Decreased appetite				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Dysphagia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Epigastric discomfort				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	2			
Gastrointestinal motility disorder				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				

subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Portal hypertensive gastropathy subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Tongue dysplasia subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Hepatobiliary disorders Cholelithiasis obstructive subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Hepatic steatosis subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Hepatitis C subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2		
Rash papular subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2		
Dry skin subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Skin ulcer subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Renal and urinary disorders			

Acute kidney injury subjects affected / exposed occurrences (all) Dysuria subjects affected / exposed occurrences (all)	 5 / 33 (15.15%) 5 2 / 33 (6.06%) 2		
Endocrine disorders Primary hypoparathyroidism subjects affected / exposed occurrences (all)	 1 / 33 (3.03%) 1		
Musculoskeletal and connective tissue disorders Muscle spasms subjects affected / exposed occurrences (all) Osteopenia subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	 3 / 33 (9.09%) 3 2 / 33 (6.06%) 2 1 / 33 (3.03%) 1 1 / 33 (3.03%) 1		
Infections and infestations Lower respiratory track infection bacterial subjects affected / exposed occurrences (all) HIV viraemia subjects affected / exposed occurrences (all) Genital candidiasis subjects affected / exposed occurrences (all) Groin abscess subjects affected / exposed occurrences (all)	 8 / 33 (24.24%) 12 5 / 33 (15.15%) 5 2 / 33 (6.06%) 2 2 / 33 (6.06%) 6		

Hepatitis C				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Appendicitis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Bacterial pyelonephritis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Body tinea				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Bronchitis bacterial				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Fungal skin infection				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Otitis externa				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Oesophageal candidiasis				

subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Onychomycosis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Oral candidiasis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Otitis media			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Pelvic inflammatory disease			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Tooth abscess			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Vascular graft infection			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Viral rash			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	11 / 33 (33.33%)		
occurrences (all)	11		
Vitamin D deficiency			
subjects affected / exposed	4 / 33 (12.12%)		
occurrences (all)	4		

Abnormal loss of weight			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Decreased appetite			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Hyperkalaemia			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Hypoglycemia			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 January 2020	Addition of a recruiting clinical site in Spain

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was stopped prematurely on 6th September 2021, without reaching the recruitment target as recruitment was difficult.
The study recruited in Ireland only and is representative of the IVDU population (mostly male and Caucasian)

Notes: