Clinical trial results:
A phase IV, open-label three-arm study investigating the impact of a combination of tenofovir disoproxil fumarate/emtricitabine with raltegravir or dolutegravir or elvitegravir/cobicistat on renal tubular function and renal transporters in HIV-1 antiretroviral naïve patients

Summary

EudraCT number	2014-004578-40
Trial protocol	GB
Global end of trial date	06 April 2017

Results information

Result version number	v1 (current)
This version publication date	22 April 2018
First version publication date	22 April 2018

Trial information

Trial identification

Sponsor protocol code	SSAT066

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02351908
WHO universal trial number (UTN)	-
Other trial identifiers	REC ref: 15/LO/0031, MHRA CTA no.: 21918/0042/001-0001

Notes:

Sponsors

Sponsor organisation name	St Stephen's AIDS Trust
Sponsor organisation address	Chelsea Chambers, 262a Fulham Road, London, United Kingdom, SW10 9EL
Public contact	Marita Marshall, St Stephen's Clinical Research, +44 203 828 0567, marita.marshall@ststcr.com
Scientific contact	Dr Greame Moyle, Chelsea and Westminster Hosptial NHS FT, geylom@gmail.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	22 January 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 April 2017
Global end of trial reached?	Yes
Global end of trial date	06 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the change in retinol-binding protein/creatinine ratio with each regimen over 24 weeks.

Protection of trial subjects:

The protocol was written, and the study was conducted according to the ICH Harmonized Tripartite Guideline on Good Clinical Practice, E6 and the principles of the Declaration of Helsinki. The protocol was approved by the National Regulator and an Independent Ethics Committee as required by national legislation. Written informed consent was obtained from each subject prior to evaluations being performed for eligibility. Subjects were given adequate time to review the information in the informed consent and were encouraged to ask questions concerning all portions of the conduct of the study to ensure understanding. The purpose of the study together with the procedures benefits and risks of the study; any discomforts and the precautions taken was described during the consent process; allowing subject to make an informed decision about participation. Subjects were also informed of their right to discontinue from the study at any time without any detriment. The inclusion/exclusion criteria were designed to eliminate subjects who may have been put at risk by participating in the study. Women of childbearing potential were required to have a negative pregnancy test at screening in order to exclude any participants who may have been pregnant, and these participants (along with heterosexually active males) were required to use effective birth control for the duration of the study. Safety and tolerability of medications were assessed by questions, physical examination (as required) and laboratory parameters. Any changes in health status during the study were recorded and followed up by the clinical team.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2015
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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	60
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 60 patients were enrolled to this study, out of the 68 patients screened. All patients were recruited from Chelsea and Westminster Hospital NHS Foundation Trust, screening began 7th Apr 2015 and continued until 17th March 2016. Their virus has to show full genetic susceptibility to NRTI class antiretrovirals, and EGFR>60ml/min

Pre-assignment

Screening details:

Patients with untreated HIV and a measured viral load >1000 copies/ml were approached for this study. They required no previous exposure to an anti-retrovrial drug (with the exception of PrEP or PEP use that is not associated with the HIV acquisition).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Raltegravir + Truvada

Arm description:

Truvada® (200mg/245mg film coated tablets) one tablet once daily +
Raltegravir 400mg (one tablet) twice daily

Arm type	Active comparator
Investigational medicinal product name	Truvada
Investigational medicinal product code	J05AR03
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Each film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300 mg of tenofovir disoproxil fumarate or 136 mg of tenofovir). Taken once daily.

Investigational medicinal product name	Raltegravir
Investigational medicinal product code	J05AX08
Other name	Isentress
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Each film-coated tablet contains 400 mg of raltegravir (as potassium). Taken twice daily.

Arm title	Dolutegravir + Truvada

Arm description:

Truvada® + Tivicay® (Dolutegravir) 50mg OD

Arm type	Active comparator
Investigational medicinal product name	Truvada
Investigational medicinal product code	J05AR03
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details: Each film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300 mg of tenofovir disoproxil fumarate or 136 mg of tenofovir). Taken once daily.	
Investigational medicinal product name	Dolutegravir
Investigational medicinal product code	J05AX12
Other name	Tivicay
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 50 mg (one tablet) orally once daily	
Arm title	Stribild
Arm description: Stribild®(150mg Elvitegravir, 150mg Cobicistat, 200mg TenofovirDF, 245mg Emtricitabine) film coated tablet, once daily.	
Arm type	Active comparator
Investigational medicinal product name	Stribild
Investigational medicinal product code	J05AR09
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Each film-coated tablet contains 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300 mg of tenofovir disoproxil fumarate or 136 mg of tenofovir). One tablet taken once daily.	

Number of subjects in period 1	Raltegravir + Truvada	Dolutegravir + Truvada	Stribild
Started	20	20	20
Week 4	19	20	20
Week 12	19	20	20
Week 24	19	20	20
Week 36	18	20	20
Week 48	18	20	19
Completed	18	20	19
Not completed	2	0	1
Physician decision	1	-	-
Lost to follow-up	1	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Raltegravir + Truvada
Reporting group description:	
Truvada® (200mg/245mg film coated tablets) one tablet once daily + Raltegravir 400mg (one tablet) twice daily	

Reporting group title	Dolutegravir + Truvada
Reporting group description:	
Truvada® + Tivicay® (Dolutegravir) 50mg OD	
Reporting group title	Stribild
Reporting group description:	
Stribild®(150mg Elvitegravir, 150mg Cobicistat, 200mg TenofovirDF, 245mg Emtricitabine) film coated tablet, once daily.	

Reporting group values	Raltegravir + Truvada	Dolutegravir + Truvada	Stribild
Number of subjects	20	20	20
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	36.0	32.2	36.8
standard deviation	± 10.0	± 8.2	± 10.0
Gender categorical Units: Subjects			
Female	1	0	2
Male	19	20	18
Ethnicity Units: Subjects			
White	15	16	15
Black	2	1	1
Asian	1	2	1
Mixed race	1	0	1
Other	1	1	2
BMI			
Body Mass Index			
Units: kg/m^2			
median	24.4	23.3	22.8

inter-quartile range (Q1-Q3)	22.0 to 26.6	19.1 to 23.3	22.4 to 26.4

Reporting group values	Total		
Number of subjects	60		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	3		
Male	57		
Ethnicity Units: Subjects			
White	46		
Black	4		
Asian	4		
Mixed race	2		
Other	4		
BMI			
Body Mass Index			
Units: kg/m^2			
median			
inter-quartile range (Q1-Q3)	-		

End points

End points reporting groups

Reporting group title	Raltegravir + Truvada
Reporting group description:	
Truvada® (200mg/245mg film coated tablets) one tablet once daily + Raltegravir 400mg (one tablet) twice daily	

Reporting group title	Dolutegravir + Truvada
Reporting group description:	
Truvada® + Tivicay® (Dolutegravir) 50mg OD	

Reporting group title	Stribild
Reporting group description:	
Stribild®(150mg Elvitegravir, 150mg Cobicistat, 200mg TenofovirDF, 245mg Emtricitabine) film coated tablet, once daily.	
Subject analysis set title	Baseline RTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Baseline time-point Raltegravir + Truvada arm	
Subject analysis set title	Week 4 RTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 4 Raltegravir + Truvada arm	
Subject analysis set title	Week 12 RTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 12 time-point Raltegravir + Truvada arm	
Subject analysis set title	Week 24 RTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 24 time-point Raltegravir + Truvada arm	
Subject analysis set title	Week 36 RTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 36 time-point Raltegravir + Truvada Arm	
Subject analysis set title	Week 48 RTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 48 time-point Ralegravir + Truvada arm	
Subject analysis set title	Baseline DTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Baseline time-point Dolutegravir + Truvada arm	
Subject analysis set title	Week 4 DTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 4 time-point Dolutegravir + Truvada arm	
Subject analysis set title	Week 12 DTG Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
Week 12 time-point Dolutegravir + Truvada arm	

Subject analysis set title	Week 24 DTG Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 24 time-point Dolutegravir + Truvada arm	
Subject analysis set title	Week 36 DTG Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 36 time-point Dolutegravir + Truvada arm	
Subject analysis set title	Week 48 DTG Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 48 time-point Dolutegravir + Truvada arm	
Subject analysis set title	Baseline Str Arm
Subject analysis set type	Full analysis
Subject analysis set description: Baseline time-point Stribild arm	
Subject analysis set title	Week 4 Str Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 4 time-point Stribild arm	
Subject analysis set title	Week 12 Str Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 12 time-point Stribild arm	
Subject analysis set title	Week 24 Str Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 24 time-point Stribild arm	
Subject analysis set title	Week 36 Str Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 36 time-point Stribild arm	
Subject analysis set title	Week 48 Str Arm
Subject analysis set type	Full analysis
Subject analysis set description: Week 48 time-point Stribild arm	

Primary: Change in retinol-binding protein/creatinine ratio (PCR) with each regimen over time.

End point title	Change in retinol-binding protein/creatinine ratio (PCR) with each regimen over time.
End point description: Change in The change in retinol-binding protein/creatinine ratio (PCR) with each regimen over time (measured via nephelometric assay run on Siemens BNII nephelometer).	
End point type	Primary
End point timeframe: Baseline, Week 4, Week 12, Week 24 & Week 48	

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	18
Units: µg/mmol				
median (inter-quartile range (Q1-Q3))				
Value	7 (6 to 10)	6 (5 to 8)	8 (6 to 10)	10 (9 to 12)
Change from baseline	0 (0 to 0)	0 (-1 to 2)	1 (-1 to 4)	3 (1 to 6)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	19	19	19
Units: µg/mmol				
median (inter-quartile range (Q1-Q3))				
Value	9 (6 to 15)	7 (6 to 11)	8 (6 to 13)	9 (7 to 14)
Change from baseline	2 (1 to 6)	0 (0 to 0)	1 (-1 to 5)	1.5 (-1 to 4)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	18	19	18
Units: µg/mmol				
median (inter-quartile range (Q1-Q3))				
Value	9 (6 to 13)	12 (8 to 17)	7 (5 to 11)	9 (6 to 13)
Change from baseline	1 (-2 to 8)	3 (0 to 7)	0 (0 to 0)	1 (-2 to 3)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	17	19	
Units: µg/mmol				
median (inter-quartile range (Q1-Q3))				
Value	10 (6 to 19)	11 (8 to 12)	12 (6 to 22)	
Change from baseline	1 (-1 to 6)	4 (1.5 to 8)	2 (0 to 9)	

Attachments (see zip file)	SSAT066 Stats RBP.pdf

Statistical analyses

Statistical analysis title	RTG Baseline to W4 Wilcoxon
Comparison groups	Baseline RTG Arm v Week 4 RTG Arm

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.773
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	RTG Baseline to W12 Wilcoxon
Comparison groups	Baseline RTG Arm v Week 12 RTG Arm
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.109
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	RTG Baseline to W24 Wilcoxon
Comparison groups	Baseline RTG Arm v Week 24 RTG Arm
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	RTG Baseline to W48 Wilcoxon
Comparison groups	Baseline RTG Arm v Week 48 RTG Arm
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.007
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	DTG Baseline to W4 Wilcoxon
Comparison groups	Baseline DTG Arm v Week 4 DTG Arm
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.109
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	DTG Baseline to W12 Wilcoxon
Comparison groups	Baseline DTG Arm v Week 12 DTG Arm
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.024
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	DTG Baseline to W24 Wilcoxon
Comparison groups	Baseline DTG Arm v Week 24 DTG Arm
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.169
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	DTG Baseline to W48 Wilcoxon
Comparison groups	Baseline DTG Arm v Week 48 DTG Arm
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.006
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Str Baseline to W4 Wilcoxon
Comparison groups	Baseline Str Arm v Week 4 Str Arm
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.324
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Str Baseline to W12 Wilcoxon
Comparison groups	Baseline Str Arm v Week 12 Str Arm
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.022
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Str Baseline to W12 Wilcoxon
Comparison groups	Baseline Str Arm v Week 24 Str Arm
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Str Baseline to W48 Wilcoxon
Comparison groups	Baseline Str Arm v Week 48 Str Arm
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.004
Method	Wilcoxon (Mann-Whitney)

Secondary: Variation from baseline of eGFR using Cockcroft Gault formula	
End point title	Variation from baseline of eGFR using Cockcroft Gault formula
End point description: The Cockcroft and Gault formula (1973) Weight measured over time.	
End point type	Secondary
End point timeframe: From baseline to Weeks 4,12,24,36 and 48	

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	18	17	19
Units: mL/min				
median (inter-quartile range (Q1-Q3))	129.5 (113.3 to 145.8)	115.7 (105.5 to 143.4)	124.1 (102.6 to 140.0)	124.3 (109.3 to 137.3)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	18	20	19
Units: mL/min				
median (inter-quartile range (Q1-Q3))	118.1 (104.3	115.9 (97.5 to	124.6 (111.4	100.1 (94.1 to

to 138.5)	141.2)	to 141.2)	118.8)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	17	17	17
Units: mL/min				
median (inter-quartile range (Q1-Q3))	104.2 (93.8 to 115.9)	104.7 (98.8 to 119.8)	106.2 (95.2 to 110.2)	99.0 (89.1 to 117.9)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	18	19
Units: mL/min				
median (inter-quartile range (Q1-Q3))	127.8 (117.0 to 143.8)	113.4 (101.9 to 133.8)	113.1 (98.2 to 141.1)	121.0 (88.2 to 140.7)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: mL/min				
median (inter-quartile range (Q1-Q3))	120.6 (96.0 to 134.1)	114.2 (103.0 to 131.1)		

Attachments (see zip file)	SSAT 066 eGFR - CG.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - MDRD with creatinine

End point title	Variation from baseline of eGFR - MDRD with creatinine

End point description:

GFR = 186 x SerumCr-1.154 * age-0.203 * 1.212 (if patient is black) * 0.742 (if female)

Source: http://www.mdcalc.com/mdrd-gfr-equation/

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	18	19
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	109.8 (97.7 to 118.3)	105.1 (95.5 to 116.8)	103.9 (92.6 to 117.9)	105.1 (96.7 to 117.1)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	20	19
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	100.9 (88.4 to 111.1)	103.0 (70.6 to 129.0)	114.6 (98.9 to 122.5)	98.1 (79.0 to 105.3)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	17	19	19
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	89.9 (78.3 to 104.5)	94.8 (87.1 to 105.6)	89.0 (77.8 to 100.0)	90.5 (71.2 to 107.0)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	18	19
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	115.7 (103.6 to 122.6)	102.3 (97.2 to 109.9)	101.7 (87.6 to 116.9)	92.5 (84.1 to 112.4)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	101.5 (85.1 to 113.0)	99.6 (88.2 to 109.0)		

Attachments (see zip file)	SSAT 066 eGFR - Creatinine.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - CKD-EPI with creatinine / cystatin-C

End point title	Variation from baseline of eGFR - CKD-EPI with creatinine / cystatin-C

End point description:

Inker LA, Schmid CH, Tighiouart H, et al. Estimating glomerular filtration rate from serum creatinine and cystatin C. N Engl J Med. 2012;367(1):20-29.

The CKD-EPI creatinine–cystatin C equation (2012) can be expressed as a single equation:
135 × min(Scr/κ, 1)α × max(Scr/κ, 1)−0.601 × min(Scys/0.8, 1)−0.375 × max(Scys/0.8, 1)−0.711 × 0.995Age [× 0.969 if female] [× 1.08 if black],

where Scr is serum creatinine,

Scys is serum cystatin C,

κ is 0.7 for females and 0.9 for males,
α is −0.248 for females and −0.207 for males,

min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1.

Change from baseline & P values are include in attached chart.

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	92.0 (83.7 to 102.6)	95.0 (86.2 to 102.8)	97.9 (89.6 to 105.2)	102.2 (97.3 to 110.7)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	19	20	20
Units: mL/min/1.73m^2				

median (inter-quartile range (Q1-Q3))	111.8 (105.2 to 113.8)	101.3 (88.6 to 107.4)	101.7 (93.8 to 107.2)	88.9 (82.9 to 99.5)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	20	20
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	91.1 (85.1 to 95.8)	95.0 (89.6 to 103.7)	106.5 (97.2 to 110.7)	100.7 (89.0 to 105.4)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	20	20
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	109.1 (97.3 to 115.6)	103.2 (91.4 to 113.0)	104.1 (87.1 to 110.3)	96.9 (90.0 to 112.3)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	111.4 (103.5 to 118.4)	104.3 (94.6 to 114.8)		

Attachments (see zip file)	SSAT 066 eGFR - CKD-EPI Creatinine & cystatin C.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - CKD-EPI with Creatinine

End point title	Variation from baseline of eGFR - CKD-EPI with Creatinine

End point description:

eGFR = 141 x min(SCr/κ, 1)α x max(SCr /κ, 1)-1.209 x 0.993Age x 1.018 [if female] x 1.159 [if Black]

Source: https://www.kidney.org/content/ckd-epi-creatinine-equation-2009

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36, 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	111.4 (100.6 to 115.3)	108.2 (99.3 to 115.0)	109.3 (99.2 to 115.6)	108.8 (99.4 to 115.6)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	19	20	20
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	106.3 (97.7 to 109.4)	107.4 (96.7 to 111.1)	112.4 (103.6 to 120.3)	101.4 (83.5 to 110.9)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	20	20
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	95.2 (83.2 to 103.9)	103.4 (93.9 to 111.4)	96.3 (83.5 to 106.0)	97.9 (79.9 to 108.7)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	20	20
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	117.5 (110.7 to 122.5)	108.6 (105.3 to 116.8)	111.0 (94.7 to 118.1)	102.9 (93.5 to 119.0)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: mL/min/1.73m^2				
median (inter-quartile range (Q1-Q3))	106.2 (93.7 to 118.9)	106.9 (96.1 to 112.1)		

Attachments (see zip file)	SSAT 066 eGFR - CKD-EPI Creatinine.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - β2-Microglobulin excretion

End point title	Variation from baseline of eGFR - β2-Microglobulin excretion
End point description: β2-Microglobulin excretion in urine.	
End point type	Secondary
End point timeframe: Change from baseline at weeks 4, 12, 28, 36 & 48.	

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	11	14
Units: ug/L				
median (inter-quartile range (Q1-Q3))	101 (63 to 399)	137 (74 to 218)	98 (40 to 310)	131 (40 to 302)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	17	10	14
Units: ug/L				
median (inter-quartile range (Q1-Q3))	105 (40 to 269)	117 (96 to 228)	115 (56 to 280)	146 (84 to 255)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	12	12	13	12
Units: ug/L				
median (inter-quartile range (Q1-Q3))	114 (46 to 242)	145 (90 to 307)	72 (58 to 103)	101 (50 to 139)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	11	13	
Units: ug/L				
median (inter-quartile range (Q1-Q3))	105 (76 to 146)	172 (40 to 561)	130 (64 to 187)	

Attachments (see zip file)	SSAT 066 eGFR - Beta-2-microglobulin excretion.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - alpha-1-Microglobulin excretion

End point title	Variation from baseline of eGFR - alpha-1-Microglobulin excretion

End point description:

Alpha-1-Microglobulin excretion in urine.

End point type	Secondary

End point timeframe:

Changed from baseline at weeks 4, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: mg/L				
median (inter-quartile range (Q1-Q3))	6 (2 to 13)	7 (3 to 13)	9 (3 to 17)	11 (3 to 18)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	19	20
Units: mg/L				
median (inter-quartile range (Q1-Q3))	9 (4 to 17)	5 (2 to 9)	5 (4 to 11)	11 (6 to 17)

End point values	Week 24 DTG	Week 48 DTG	Baseline Str	Week 4 Str

	Arm	Arm	Arm	Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	19
Units: mg/L				
median (inter-quartile range (Q1-Q3))	7 (5 to 17)	9 (5 to 16)	3 (2 to 7)	4 (2 to 16)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	20	20	
Units: mg/L				
median (inter-quartile range (Q1-Q3))	7 (3 to 19)	6 (3 to 26)	10 (2 to 19)	

Attachments (see zip file)	SSAT 066 eGFR - alpha-1-microglobulin excretion.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - urinary microalbumin/creatinine ratio

End point title	Variation from baseline of eGFR - urinary microalbumin/creatinine ratio

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	12	12	13
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	0.6 (0.5 to 2.2)	0.6 (0.4 to 1.1)	0.7 (0.4 to 2.1)	0.6 (0.3 to 1.6)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	17	12	17
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	0.5 (0.4 to 0.6)	0.5 (0.4 to 1.1)	0.7 (0.5 to 1.5)	0.9 (0.3 to 1.2)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	14	13	11
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	0.7 (0.4 to 1.2)	0.4 (0.4 to 0.9)	0.6 (0.5 to 1.0)	0.6 (0.4 to 1.0)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	14	15	
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	0.6 (0.4 to 1.0)	0.7 (0.4 to 1.7)	0.9 (0.4 to 1.9)	

Attachments (see zip file)	SSAT 066 eGFR - Urinary albumin & creatinine ratio.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - protein/creatinine ratio

End point title	Variation from baseline of eGFR - protein/creatinine ratio

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	17	18	17
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	9 (6 to 10)	8 (6 to 9)	8 (6 to 11)	9 (7 to 12)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	15	20	15	18
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	8 (6 to 9)	7 (5 to 8)	7 (5 to 8)	8 (6 to 9)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	17	19	14
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	7 (5 to 9)	7 (6 to 9)	6 (5 to 8)	8 (6 to 9)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	17	17	16	
Units: mg/mmol				
median (inter-quartile range (Q1-Q3))	9 (8 to 10)	8 (7 to 11)	7 (6 to 12)	

Attachments (see zip file)	SSAT 066 eGFR - Urinary protien & creatinine ratio.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - Fractional phosphate excretion (fasted plasma PO4)

End point title	Variation from baseline of eGFR - Fractional phosphate excretion (fasted plasma PO4)

End point description:

Fractional phosphate excretion (fasted plasma phosphate and urinary spot phosphate)
From the protocol: Fractional phosphate excretion (FEPi): {[PO4 (U) x Cr (S)] /[PO4 (S) x Cr (U)]} x100

http://www.scymed.com/en/smnxps/pshpb390.htm

Our Lab uses phosphate in mmol/L instead of mEq/L, so if that is the case you can use for Creatinine in the serum umol/L and for Creatinine in the urine mmol/L.
Serum creatinine unit in SSAT 066 database is in umol/L.

End point type	Secondary

End point timeframe:

Changed from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	18	19
Units: percent				
median (inter-quartile range (Q1-Q3))	7 (6.0 to 9.5)	9.7 (5.2 to 15.3)	11.2 (9.3 to 13.5)	9.3 (6.7 to 14.9)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	18	20
Units: percent				
median (inter-quartile range (Q1-Q3))	9.8 (7.7 to 13.3)	8.5 (5.5 to 9.9)	11.6 (7.1 to 14.7)	12.0 (9.2 to 17.0)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	19	20	16
Units: percent				
median (inter-quartile range (Q1-Q3))	11.2 (7.1 to 12.9)	9.5 (6.8 to 13.1)	9.1 (7.3 to 14.5)	12.0 (9.3 to 17.3)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	16	19	20	
Units: percent				
median (inter-quartile range (Q1-Q3))	13.2 (7.5 to 16.2)	10.8 (7.1 to 16.0)	10.5 (8.6 to 17.7)	

Attachments (see zip file)	SSAT 066 eGFR - Fractional phosphate excretion (fasted

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - Fractional phosphate excretion (urine spot phosphate)

End point title	Variation from baseline of eGFR - Fractional phosphate excretion (urine spot phosphate)

End point description:

Fractional phosphate excretion (fasted plasma phosphate and urinary spot phosphate)

From the protocol: Fractional phosphate excretion (FEPi): {[PO4 (U) x Cr (S)] /[PO4 (S) x Cr (U)]} x100

http://www.scymed.com/en/smnxps/pshpb390.htm

Our Lab uses phosphate in mmol/L instead of mEq/L, so if that is the case you can use for Creatinine in the serum umol/L and for Creatinine in the urine mmol/L.
Serum creatinine unit in SSAT 066 database is in umol/L.

End point type	Secondary

End point timeframe:

Changed from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	17.9 (7.9 to 22.7)	15.4 (8.5 to 22.9)	20.1 (9.4 to 27.5)	20.9 (10.9 to 33.8)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	19	20
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	17.3 (9.6 to 27.7)	16.4 (8.7 to 19.2)	15.9 (7.7 to 25.6)	19.5 (11.4 to 34.8)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	16.9 (8.0 to 25.9)	11.8 (6.7 to 19.4)	13.2 (9.0 to 29.0)	18.8 (9.6 to 22.0)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	20	20	
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	19.6 (5.8 to 27.3)	19.6 (7.1 to 28.5)	17.5 (6.5 to 22.4)	

Attachments (see zip file)	SSAT 066 eGFR - Fractional phosphate excretion (urinary spot

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - Plasma urate

End point title	Variation from baseline of eGFR - Plasma urate

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at week 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	18	19
Units: µmol/L				
median (inter-quartile range (Q1-Q3))	366 (296 to 438)	371 (326 to 413)	365 (330 to 416)	342 (320 to 379)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	19	20
Units: µmol/L				
median (inter-quartile range (Q1-Q3))	389 (284 to 413)	367 (324 to 412)	354 (344 to 387)	376 (345 to 407)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	19	19	19
Units: µmol/L				
median (inter-quartile range (Q1-Q3))	378 (358 to 430)	366 (348 to 379)	360 (297 to 393)	357 (297 to 390)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	19	18
Units: µmol/L				
median (inter-quartile range (Q1-Q3))	308 (294 to 390)	324 (288 to 367)	311 (275 to 347)	315 (277 to 358)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	20		
Units: µmol/L				
median (inter-quartile range (Q1-Q3))	320 (267 to 367)	329 (264 to 391)		

Attachments (see zip file)	SSAT 066 eGFR - Plasma Urate.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of eGFR - glycosuria

End point title	Variation from baseline of eGFR - glycosuria

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: mmol/FL				
median (inter-quartile range (Q1-Q3))	0.4 (0.2 to 0.5)	0.3 (0.2 to 0.4)	0.3 (0.2 to 0.4)	0.4 (0.1 to 0.5)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	19	20
Units: mmol/FL				
median (inter-quartile range (Q1-Q3))	0.4 (0.2 to 0.4)	0.3 (0.2 to 0.4)	0.3 (0.2 to 0.5)	0.4 (0.3 to 0.5)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	19
Units: mmol/FL				
median (inter-quartile range (Q1-Q3))	0.3 (0.2 to 0.5)	0.3 (0.1 to 0.4)	0.3 (0.2 to 0.4)	0.3 (0.1 to 0.3)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	20	20	
Units: mmol/FL				
median (inter-quartile range (Q1-Q3))	0.3 (0.1 to 0.4)	0.4 (0.1 to 0.5)	0.3 (0.1 to 0.4)	

Attachments (see zip file)	SSAT 066 eGFR - Urine Glucose.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients achieving virologic response

End point title	Proportion of patients achieving virologic response

End point description:

Virologic response was measured as HIV RNA < 40 cp/mL.

All patients had >40cp/ml at baesline (inclusion criteria)

End point type	Secondary

End point timeframe:

The proportion of patients achieving virologic response at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	18	19
Units: Patients	0	11	17	19

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	20	20
Units: Patients	16	17	0	15

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	18	19
Units: Patients	19	18	17	17

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	20	18
Units: Patients	0	15	20	16

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	20		
Units: Patients	14	17		

Attachments (see zip file)	SSAT 066 Proportion of patients HIV less than 40cp per mL.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation in immunologic markers - CD4+

End point title	Variation in immunologic markers - CD4+

End point description:

End point type	Secondary

End point timeframe:

Changes in immunological markers at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	19	19
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	450 (412 to 541)	559 (448 to 676)	587 (450 to 742)	604 (479 to 859)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	20	20
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	611 (499 to 725)	614 (473 to 833)	488 (353 to 622)	554 (471 to 617)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	18
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	607 (561 to 809)	648 (578 to 799)	600 (489 to 847)	629 (566 to 761)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	20	20	20
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	548 (444 to 800)	671 (455 to 776)	682 (452 to 887)	652 (512 to 861)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	688 (542 to 978)	664 (511 to 960)		

Attachments (see zip file)	SSAT 066 immological markers - CD4.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation in immunologic markers - CD8+

End point title	Variation in immunologic markers - CD8+

End point description:

End point type	Secondary

End point timeframe:

Changes in immunologic markers at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	19	19
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	900 (730 to 1144)	888 (668 to 1091)	818 (675 to 981)	842 (695 to 946)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	20	20
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	747 (669 to 838)	734 (556 to 840)	1187 (907 to 1456)	998 (749 to 1269)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	18
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	1157 (968 to 1522)	1151 (849 to 1402)	977 (678 to 1303)	911 (717 to 1125)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	20	20	20
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	996 (584 to 1184)	794 (596 to 1055)	747 (600 to 994)	635 (497 to 910)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: cells/µL				
median (inter-quartile range (Q1-Q3))	694 (491 to 1010)	744 (492 to 861)		

Attachments (see zip file)	SSAT 066 immological markers - CD8.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation in immunologic markers - CD4:CD8 Ratio

End point title	Variation in immunologic markers - CD4:CD8 Ratio

End point description:

A normal CD4/CD8 ratio is 2.0, with CD4 lymphocytes equal to or greater than 400/mm3 and CD8 lymphocytes equal to 200 to 800/mm3.

End point type	Secondary

End point timeframe:

Changes at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	19	19
Units: CD4:CD8 ratio				
median (inter-quartile range (Q1-Q3))	0.5 (0.4 to 0.7)	0.7 (0.5 to 0.7)	0.7 (0.5 to 1.0)	0.7 (0.6 to 1.0)

End point values	Week 36 RTG	Week 48 RTG	Baseline DTG	Week 4 DTG

	Arm	Arm	Arm	Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	20	20
Units: CD4:CD8 ratio				
median (inter-quartile range (Q1-Q3))	0.8 (0.7 to 1.2)	0.9 (0.8 to 1.1)	0.5 (0.3 to 0.6)	0.6 (0.4 to 0.7)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	18
Units: CD4:CD8 ratio				
median (inter-quartile range (Q1-Q3))	0.6 (0.4 to 0.8)	0.6 (0.5 to 0.9)	0.7 (0.5 to 0.9)	0.7 (0.5 to 0.9)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	20	20	20
Units: CD4:CD8 ratio				
median (inter-quartile range (Q1-Q3))	0.7 (0.4 to 1.0)	0.9 (0.6 to 1.1)	0.9 (0.7 to 1.1)	0.9 (0.7 to 1.2)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: CD4:CD8 ratio				
median (inter-quartile range (Q1-Q3))	0.9 (0.7 to 1.5)	1.1 (0.8 to 1.3)		

Attachments (see zip file)	SSAT 066 immological markers - CD4-CD8 Ratio.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation in inflammatory markers - hsCRP

End point title	Variation in inflammatory markers - hsCRP

End point description:

End point type	Secondary

End point timeframe:

At weeks 4, 12 ,24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: mg/L				
median (inter-quartile range (Q1-Q3))	1.2 (0.8 to 1.2)	1.4 (0.8 to 2.8)	1.0 (0.7 to 2.4)	0.9 (0.6 to 3.1)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	20	20
Units: mg/L				
median (inter-quartile range (Q1-Q3))	0.9 (0.6 to 1.4)	1.2 (0.8 to 2.1)	0.9 (0.6 to 1.6)	1.9 (1.1 to 3.6)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	20
Units: mg/L				
median (inter-quartile range (Q1-Q3))	1.5 (0.9 to 3.2)	1.2 (0.8 to 2.6)	1.2 (0.7 to 2.9)	1.5 (0.7 to 3.2)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	20	20	
Units: mg/L				
median (inter-quartile range (Q1-Q3))	1.9 (0.6 to 3.6)	1.7 (0.7 to 3.9)	1.4 (0.7 to 2.0)	

Attachments (see zip file)	SSAT 066 Inflammatory markers - hsCRP.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation in inflammatory markers - IL-6

End point title	Variation in inflammatory markers - IL-6

End point description:

End point type	Secondary

End point timeframe:

Change at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: pg/mL				
median (inter-quartile range (Q1-Q3))	2.6 (1.5 to 3.5)	3.1 (1.8 to 3.7)	2.6 (1.5 to 3.6)	2.5 (1.7 to 5.5)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	20	19
Units: pg/mL				
median (inter-quartile range (Q1-Q3))	1.5 (1.5 to 1.9)	2.0 (1.5 to 2.8)	2.1 (1.5 to 3.4)	2.3 (1.5 to 3.4)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	20
Units: pg/mL				
median (inter-quartile range (Q1-Q3))	2.5 (1.5 to 2.9)	1.5 (1.5 to 2.8)	1.9 (1.5 to 2.6)	2.9 (1.6 to 4.7)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	20	20	
Units: pg/mL				
median (inter-quartile range (Q1-Q3))	1.8 (1.5 to 3.7)	1.5 (1.5 to 4.0)	1.5 (1.5 to 2.7)	

Attachments (see zip file)	SSAT 066 Inflammatory markers - IL-6.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation in inflammatory markers - d-dimer

End point title	Variation in inflammatory markers - d-dimer

End point description:

End point type	Secondary

End point timeframe:

Change at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	19	19
Units: ng/mL				
median (inter-quartile range (Q1-Q3))	215 (190 to 370)	190 (190 to 330)	190 (190 to 330)	190 (190 to 250)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	20	20	20
Units: ng/mL				
median (inter-quartile range (Q1-Q3))	190 (190 to 230)	190 (190 to 325)	190 (190 to 215)	210 (190 to 290)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	20
Units: ng/mL				
median (inter-quartile range (Q1-Q3))	205 (190 to 255)	205 (190 to 2550)	200 (190 to 310)	190 (190 to 190)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	20	20	
Units: ng/mL				
median (inter-quartile range (Q1-Q3))	190 (190 to 200)	190 (190 to 210)	190 (190 to 205)	

Attachments (see zip file)	SSAT 066 Inflammatory markers - d-dimer.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of metabolic markers - Lipids (Total Cholesterol)

End point title	Variation from baseline of metabolic markers - Lipids (Total Cholesterol)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	4.7 (3.8 to 5.5)	4.2 (3.6 to 5.5)	4.5 (3.6 to 5.3)	4.0 (3.7 to 5.0)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	19	20
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	4.4 (3.3 to 4.8)	4.6 (3.9 to 5.2)	4.3 (3.6 to 5.1)	4.1 (3.6 to 5.0)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	20	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	4.1 (3.5 to 4.8)	4.4 (3.3 to 4.9)	4.1 (3.7 to 4.8)	4.3 (3.8 to 4.9)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	4.1 (3.9 to 5.1)	4.2 (3.8 to 5.3)	4.3 (4.1 to 5.0)	4.5 (4.3 to 5.6)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	19		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	4.3 (3.8 to 5.2)	4.4 (3.9 to 4.8)		

Attachments (see zip file)	SSAT 066 metabolic markers - Lipids (Total Cholesterol).pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of metabolic markers - Lipids (LDL)

End point title	Variation from baseline of metabolic markers - Lipids (LDL)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	2.9 (2.2 to 3.5)	2.7 (2.3 to 3.9)	2.6 (2.4 to 3.6)	2.5 (2.3 to 3.3)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	19	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	2.9 (2.2 to 3.1)	2.9 (2.4 to 3.5)	2.7 (2.2 to 3.1)	2.5 (2.0 to 3.3)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	20	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	2.5 (2.0 to 3.2)	2.7 (2.0 to 3.2)	2.5 (2.1 to 3.0)	2.7 (2.2 to 3.1)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	17	17
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	2.7 (2.2 to 3.3)	2.7 (2.1 to 3.3)	2.8 (2.5 to 3.5)	3.1 (2.6 to 3.8)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	19		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	2.6 (2.3 to 3.4)	2.7 (2.2 to 3.0)		

Attachments (see zip file)	SSAT 066 metabolic markers - Lipids (LDL).pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of metabolic markers - Lipids (HDL)

End point title	Variation from baseline of metabolic markers - Lipids (HDL)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.2 (0.9 to 1.5)	1.0 (0.9 to 1.3)	1.0 (1.0 to 1.2)	1.2 (1.0 to 1.3)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	19	20
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.1 (0.9 to 1.3)	1.3 (1.1 to 1.5)	1.1 (0.8 to 1.3)	1.0 (0.9 to 1.2)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	20	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.0 (0.9 to 1.2)	1.0 (0.8 to 1.3)	1.1 (1.0 to 1.4)	1.1 (0.9 to 1.4)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.1 (0.9 to 1.3)	1.1 (0.9 to 1.3)	1.1 (0.9 to 1.2)	1.2 (1.0 to 1.4)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	19		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.1 (1.0 to 1.4)	1.3 (1.1 to 1.7)		

Attachments (see zip file)	SSAT 066 metabolic markers - Lipids (HDL).pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of metabolic markers - Lipids (Triglycerides)

End point title	Variation from baseline of metabolic markers - Lipids (Triglycerides)

End point description:

End point type	Secondary

End point timeframe:

Change from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.0 (0.8 to 1.5)	0.8 (0.6 to 1.3)	0.8 (0.6 to 1.1)	0.8 (0.7 to 1.4)

End point values	Week 36 RTG Arm	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	19	20
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	0.9 (0.6 to 1.1)	0.8 (0.6 to 1.3)	1.0 (0.8 to 1.5)	0.9 (0.7 to 1.4)

End point values	Week 12 DTG Arm	Week 24 DTG Arm	Week 36 DTG Arm	Week 48 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	18	20	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	0.8 (0.7 to 1.3)	1.1 (0.9 to 1.2)	0.9 (0.7 to 1.4)	1.2 (0.8 to 1.6)

End point values	Baseline Str Arm	Week 4 Str Arm	Week 12 Str Arm	Week 24 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	20	17	18
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	0.9 (0.7 to 1.4)	1.2 (0.8 to 1.4)	0.9 (0.8 to 1.2)	1.1 (0.9 to 1.7)

End point values	Week 36 Str Arm	Week 48 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	19		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.1 (0.8 to 1.7)	0.8 (0.7 to 1.4)		

Attachments (see zip file)	SSAT 066 metabolic markers - Lipids (Triglycerides).pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of metabolic markers - Insulin

End point title	Variation from baseline of metabolic markers - Insulin

End point description:

Fasting Insulin Resistance Index
(FIRI =fasting glucose × fasting insulin/25) - Duncan MH, Singh BM, Wise PH, Carter G, Alaghband-Zadeh J: A simple measure of insulin resistance. Lancet. 1995, 346: 120-121.

End point type	Secondary

End point timeframe:

Change from baseline at week 24.

End point values	Baseline RTG Arm	Week 24 RTG Arm	Baseline DTG Arm	Week 24 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	18	17	19
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.5 (0.9 to 3.1)	1.5 (0.9 to 2.0)	1.1 (0.9 to 1.4)	1.3 (1.1 to 2.2)

End point values	Baseline Str Arm	Week 24 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	19		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	0.9 (0.6 to 1.2)	1.1 (0.7 to 1.4)		

Attachments (see zip file)	SSAT 066 Metabolic markers - Insulin.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Variation from baseline of metabolic markers - Homeostatic Model Assessment (HOMA i)

End point title	Variation from baseline of metabolic markers - Homeostatic Model Assessment (HOMA i)

End point description:

Homeostatic model assessment (HOMA) is a method for assessing β-cell function and insulin resistance (IR) from basal (fasting) glucose and insulin or C-peptide concentrations.

HOMA index: (fasting glucose in mmol/L x fasting insulin in mU/L) / 22.5

End point type	Secondary

End point timeframe:

Change from baseline at week 24.

End point values	Baseline RTG Arm	Week 24 RTG Arm	Baseline DTG Arm	Week 24 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	18	19	20
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.6 (1.0 to 4.2)	1.6 (1.0 to 2.2)	1.2 (1.0 to 2.4)	1.4 (1.0 to 2.3)

End point values	Baseline Str Arm	Week 24 Str Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	19		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))	1.0 (0.7 to 1.7)	1.2 (0.7 to 1.6)		

Attachments (see zip file)	SSAT 066 metabolic markers - HOMA.pdf

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Variation from baseline of eGFR - Urinary cystatin-C/creatinine ratio

End point title	Variation from baseline of eGFR - Urinary cystatin-C/creatinine ratio

End point description:

End point type	Other pre-specified

End point timeframe:

Changed from baseline at weeks 4, 12, 24, 36 & 48.

End point values	Baseline RTG Arm	Week 4 RTG Arm	Week 12 RTG Arm	Week 24 RTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	19	19	19
Units: ug/mmol				
median (inter-quartile range (Q1-Q3))	4.9 (4.3 to 6.6)	5.6 (4.4 to 6.5)	5.4 (4.4 to 6.7)	5.3 (4.0 to 6.3)

End point values	Week 48 RTG Arm	Baseline DTG Arm	Week 4 DTG Arm	Week 12 DTG Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	19	19	20
Units: ug/mmol				
median (inter-quartile range (Q1-Q3))	5.0 (3.9 to 6.3)	5.3 (4.5 to 7.1)	5.0 (4.1 to 5.8)	5.0 (4.0 to 9.9)

End point values	Week 24 DTG Arm	Week 48 DTG Arm	Baseline Str Arm	Week 4 Str Arm
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	19	20	19
Units: ug/mmol				
median (inter-quartile range (Q1-Q3))	5.2 (4.9 to 5.6)	5.1 (3.5 to 5.8)	5.8 (4.0 to 6.8)	5.3 (4.5 to 6.9)

End point values	Week 12 Str Arm	Week 24 Str Arm	Week 48 Str Arm	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	20	20	
Units: ug/mmol				
median (inter-quartile range (Q1-Q3))	5.3 (4.4 to 6.6)	5.1 (4.0 to 6.6)	6.0 (4.8 to 7.1)	

Attachments (see zip file)	SSAT 066 eGFR - Urinary cystatin-C & creatinine ratio.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Screening to Week 48	
Adverse event reporting additional description:	
Subjects questionned at each study visit for AEs. AEs then graded by the ACTG adverse events scale before adding to CRF.	
Assessment type	Systematic

Dictionary used	
Dictionary name	ACTG Adverse Events
Dictionary version	Dec 2004

Reporting groups	
Reporting group title	Raltegravir + Truvada
Reporting group description:	
Truvada® (200mg/245mg film coated tablets) one tablet once daily + Raltegravir 400mg (one tablet) twice daily	
Reporting group title	Dolutegravir + Truvada
Reporting group description:	
Truvada® + Tivicay® (Dolutegravir) 50mg OD	
Reporting group title	Stribild
Reporting group description:	
Stribild®(150mg Elvitegravir, 150mg Cobicistat, 200mg TenofovirDF, 245mg Emtricitabine) film coated tablet, once daily.	

Serious adverse events	Raltegravir + Truvada	Dolutegravir + Truvada	Stribild
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Diarrhoea + Vomitting	Additional description: Hospitalisation		
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea + abdominal pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Hepatitis C	Additional description: Acute Hepatitis C infection		

subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Raltegravir + Truvada	Dolutegravir + Truvada	Stribild
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	20 / 20 (100.00%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cyst (eyelid)			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Cyst (testicular)			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Kidney cyst			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Surgical and medical procedures			
Laparotomy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemorrhoid operation			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Biopsy skin			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Duodenal removal			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Wrist surgery			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Cold and cough			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hair loss			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nasal congestion and headache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nose injury (BMX accident)			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pain in R Groin			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sore throat + cough			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Abdominal pain period related			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Penile discharge	Additional description: Gonorrhea related		
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchitis			

subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Nasal congestion			
subjects affected / exposed	2 / 20 (10.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
decreased libido			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Vivid dreams			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	3 / 20 (15.00%)
occurrences (all)	0	2	3
low mood			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
low mood/depression			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
low mood/anxiety			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nightmares			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
depression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 20 (0.00%)	3 / 20 (15.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0

Stress			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Tiredness	Additional description: inc drowziness		
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
Fatigue			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Fine tremour in head	Additional description: (possibly due to anxiety)		
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	6 / 20 (30.00%)
occurrences (all)	1	1	6
Insomnia			
subjects affected / exposed	0 / 20 (0.00%)	5 / 20 (25.00%)	2 / 20 (10.00%)
occurrences (all)	0	5	2
Migraine			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Reduced concentration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Sleep disturbance			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	3 / 20 (15.00%)
occurrences (all)	1	2	3
Ear and labyrinth disorders			
Dx of degenerative hearing disease bilateral (L>R)			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Episodes of sinusitits			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
External otitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hayfever (Sinusitits)			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Worsening of tinnitus			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Uveitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Lymphogranuloma venereum (not confirmed)			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Abdominal Cramps			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Abdominal discomfort & flatulance			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Anal Fissures			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Anal Tenderness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Bleeding Gums			

subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Bloating			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	2	2	0
Bloating & Burping			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	2 / 20 (10.00%)	5 / 20 (25.00%)	3 / 20 (15.00%)
occurrences (all)	2	5	3
Dyspepsia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Heartburn			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Internal haemorrhoids			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Loose Stools			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	2 / 20 (10.00%)
occurrences (all)	0	2	2
Nausea			

subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Nausea & vommiting			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Rectal bleeding			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Rectal pain & Bleeding (LGV)			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Rectal Tear			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Sore Throat			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
Tooth broken			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
Viral Gastroenteritis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Vomitting and diarrhoea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	20	0
Epigastric pain and dyspepsia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dandruff			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Dry skin			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
irritated scalp			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Perianal ulverative lesions			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pityriasis versicolor			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Karposis Sarcome lesion	Additional description: right arm		
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Blister			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	2 / 20 (10.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Swelling face	Additional description: Upper eye lid		
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Aching joint			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	2 / 20 (10.00%)
occurrences (all)	1	2	2
bilateral foot pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
C2-C4 arthopathy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
joint pain left hand			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
minor right shoulder trauma			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Right flank pain unspecified			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Camphylobacter Gastroenteritis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Athletes foot			

subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
chest infection			
subjects affected / exposed	3 / 20 (15.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Chlamydial infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Cold			
subjects affected / exposed	4 / 20 (20.00%)	6 / 20 (30.00%)	5 / 20 (25.00%)
occurrences (all)	4	6	5
Cold upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
cold with flu-like symptoms			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
fever			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Gonorrhoea			
subjects affected / exposed	1 / 20 (5.00%)	3 / 20 (15.00%)	3 / 20 (15.00%)
occurrences (all)	1	3	3
Influenza	Additional description: 'flu like syndrome'		
subjects affected / exposed	3 / 20 (15.00%)	3 / 20 (15.00%)	6 / 20 (30.00%)
occurrences (all)	3	3	6
Gonorrhoea (throat)			
subjects affected / exposed	2 / 20 (10.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
HSV2 infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Kaposi's sarcoma			

subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
lower respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
rectal ghonorrhea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Primary Herpetic Infect			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
right foot skin bacterial infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Shingles			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Stomach infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Syphilis			
subjects affected / exposed	1 / 20 (5.00%)	5 / 20 (25.00%)	1 / 20 (5.00%)
occurrences (all)	1	5	1
Tinea Pedis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tinea unguium			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			

Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	2 / 20 (10.00%) 2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 January 2015	Clarification to acceptable birth control methods - requirement for initial study approval
14 April 2015	Corrections to exclusion criteria
11 February 2016	Addition of a PK analysis timepoint to samples already collected for a the study

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported