Clinical trial results:
A Phase IIIb, randomized, open-label study of the safety and efficacy of dolutegravir/abacavir/lamivudine once daily compared to atazanavir and ritonavir plus tenofovir/emtricitabine once daily in HIV-1 infected antiretroviral therapy naïve women

Summary

EudraCT number	2012-005823-34
Trial protocol	GB IT ES PT FR
Global end of trial date	

Results information

Result version number	v1
This version publication date	10 August 2016
First version publication date	10 August 2016

Trial information

Trial identification

Sponsor protocol code	ING117172

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1-866 4357343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1-866 4357343,

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	Interim
Date of interim/final analysis	15 January 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 September 2015
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferior antiviral activity of DTG/ABC/3TC FDC once daily compared to ATV+RTV+TDF/FTC FDC each administered once daily over 48 weeks in HIV-1 infected ART naïve women.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 August 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Ethical reason
Long term follow-up duration	4 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 134
Country: Number of subjects enrolled	South Africa: 66
Country: Number of subjects enrolled	Russian Federation: 50
Country: Number of subjects enrolled	Argentina: 44
Country: Number of subjects enrolled	Thailand: 40
Country: Number of subjects enrolled	Canada: 20
Country: Number of subjects enrolled	Puerto Rico: 2
Country: Number of subjects enrolled	Mexico: 11
Country: Number of subjects enrolled	Portugal: 9
Country: Number of subjects enrolled	Spain: 54
Country: Number of subjects enrolled	United Kingdom: 25
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Italy: 28
Worldwide total number of subjects	499
EEA total number of subjects	132

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)	493
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study consists of a Screening (14-28 days), Randomized (48 weeks) and Continuation (Cont.) Phase. Participants were said to have completed the study if they completed the Randomized phase and did not enter the Cont. Phase. Participants entering the Cont. Phase were said to have completed the study if they completed both phases of the study.

Pre-assignment

Screening details:

A total of 499 participants were randomized to receive dolutegravir (DTG)/ abacavir (ABC)/ lamivudine (3TC) fixed dose combination (FDC) or combination of atazanavir (ATV), Ritonavir (RTV) and FDC of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC). A total of 495 participants received at least single dose of investigational products (IP).

Period 1

Period 1 title	Randomized phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD

Arm description:

Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants on this arm who successfully completed the Randomized Phase were allowed access to DTG/ABC/3TC FDC in the Continuation Phase until it was i) locally approved and commercially available, or ii) the participant no longer derived clinical benefit or iii) the participant met a protocol-defined reason for discontinuation, or iv) development of DTG/ABC/3TC FDC was discontinued/terminated.

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

Dosage and administration details:

Participants received Dolutegravir (DTG)/ abacavir (ABC)/ lamivudine (3TC) 50 mg/600 mg/300 mg tablet once daily orally for 48 weeks.

Arm title	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD

Arm description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks.

Arm type	Active comparator
Investigational medicinal product name	Atazanavir (ATV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received ATV 300 mg capsule along with RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks.

Investigational medicinal product name	Ritonavir (RTV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received RTV 100 mg tablet along with ATV 300 mg capsule and TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks

Investigational medicinal product name	Disoproxil fumarate/ emtricitabine (TDF/FTC).
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received TDF/FTC FDC 300 mg/200 mg tablet along with ATV 300 mg capsule and RTV 100 mg tablet once daily orally for 48 weeks

Number of subjects in period 1[1]	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Started	248	247
Completed	206	192
Not completed	42	55
Adverse event, serious fatal	1	-
Physician decision	1	-
Consent withdrawn by subject	5	7
Adverse event, non-fatal	9	18
Lost to follow-up	11	13
Lack of efficacy	5	4
Protocol deviation	10	13

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Justification for difference in the number of enrolled and the number of patients who received drugs: 1 participant withdrew consent, 1 participant was excluded at the investigator's discretion, 2 participants were entered in error (1 pregnant, 1 had resistance mutations).

Period 2

Period 2 title	Continuation phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD

Arm description:

Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants on this arm who successfully completed the Randomized Phase were allowed access to DTG/ABC/3TC FDC in the Continuation Phase until it was i) locally approved and commercially available, or ii) the participant no longer derived clinical benefit or iii) the participant met a protocol-defined reason for discontinuation, or iv) development of DTG/ABC/3TC FDC was discontinued/terminated.

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

Dosage and administration details:

Participants received Dolutegravir (DTG)/ abacavir (ABC)/ lamivudine (3TC), 50 mg/600 mg/300 mg tablet once daily orally for 48 weeks.

Number of subjects in period 2[2]	DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Started	120
Ongoing	84
Completed	30
Not completed	90
Adverse event, serious fatal	1
Consent withdrawn by subject	2
Ongoing	84
Protocol deviation	3

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: As per protocol, subjects are entered into the Continuation Phase only if i) the subject is randomized to the DTG/ABC/3TC FDC group, ii) the subject successfully completes 48 weeks of treatment, iii) DTG/ABC/3TC FDC is not locally approved or commercially available, and iii) the subject continues to derives clinical benefit, and does not meet a protocol-defined reason for discontinuation.

Baseline characteristics

Reporting groups	
Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Reporting group description:	
Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants on this arm who successfully completed the Randomized Phase were allowed access to DTG/ABC/3TC FDC in the Continuation Phase until it was i) locally approved and commercially available, or ii) the participant no longer derived clinical benefit or iii) the participant met a protocol-defined reason for discontinuation, or iv) development of DTG/ABC/3TC FDC was discontinued/terminated.	
Reporting group title	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Reporting group description:	
Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks.	

Reporting group values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD	Total
Number of subjects	248	247	495
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	38.1	37.8	
standard deviation	± 11.15	± 10.14	-
Gender categorical			
Units: Subjects			
Female	248	247	495
Male	0	0	0
Race			
Units: Subjects			
African American/African Heritage	102	108	210
American Indian Or Alaskan Native	6	7	13
Asian - Central/South Asian Heritage	2	0	2
Asian - East Asian Heritage	0	1	1
Asian - South East Asian Heritage	20	22	42
Native Hawaiian Or Other Pacific Islander	1	0	1
White - Arabic/North African Heritage	3	3	6
White - White/Caucasian/European Heritage	112	104	216
Mixed Race	2	2	4

End points

End points reporting groups

Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Reporting group description:	
Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants on this arm who successfully completed the Randomized Phase were allowed access to DTG/ABC/3TC FDC in the Continuation Phase until it was i) locally approved and commercially available, or ii) the participant no longer derived clinical benefit or iii) the participant met a protocol-defined reason for discontinuation, or iv) development of DTG/ABC/3TC FDC was discontinued/terminated.	
Reporting group title	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Reporting group description:	
Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks.	
Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Reporting group description:	
Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants on this arm who successfully completed the Randomized Phase were allowed access to DTG/ABC/3TC FDC in the Continuation Phase until it was i) locally approved and commercially available, or ii) the participant no longer derived clinical benefit or iii) the participant met a protocol-defined reason for discontinuation, or iv) development of DTG/ABC/3TC FDC was discontinued/terminated.	

Primary: Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48

End point title	Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48
End point description:	
Percentage of participants with plasma human immunodeficiency virus type 1(HIV-1) ribonucleic acid (RNA) <50 copies per milliliter (c/mL) were assessed at Week 48 using the Snapshot algorithm. Analysis was performed using a stratified analysis with Cochran-Mantel-Haenszel (CMH) weights, adjusting for Baseline plasma HIV-1 RNA (=<vs. >100,000 c/mL) and CD4+ cell count (=<350 cells per millimetre cube (cells/mm^3) or >350 cells/mm^3). Intent-to-Treat Exposed (ITT-E) Population comprised of all randomized participants who received at least one dose of study medication.	
End point type	Primary
End point timeframe:	
Week 48	

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[1]	247[2]		
Units: Percentage of Participants				
number (not applicable)	82	71		

Notes:

[1] - ITT-E population

[2] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Hypothesis was to show that the antiviral effect of the DTG/ABC/3TC FDC administered QD was non-inferior to QD ATV+RTV+TDF/FTC FDC. Non-inferiority was concluded if the lower bound of a two-sided 95% confidence interval for the difference in response rates between the two treatment arms was greater than -12%.

Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.005 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted difference in proportion
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	17.8

Notes:

[3] - If the primary and PP analyses both demonstrated non-inferiority, then as per pre-specified analysis, superiority of DTG/ABC/3TC FDC versus ATV+RTV+TDF/FTC FDC was tested in the ITT-E population at the 2-sided 5% level of significance.

Secondary: Percentage of participants with plasma HIV-1 RNA <50 and <400 c/mL over time

End point title	Percentage of participants with plasma HIV-1 RNA <50 and <400 c/mL over time

End point description:

Percentage of participants with plasma HIV-1 RNA <50 and <400 c/mL were assessed at Baseline, Week 4, 12, 24 , 36 and Week 48 using the Snapshot algorithm (Missing, Switch or Discontinuation = Failure). The Baseline value was defined as the latest pre-dose assessment (Day 1) value. A value of "99999" indicates where no data is available or not able to determine the value.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[4]	247[5]		
Units: Percentage of Participants				
number (not applicable)				
HIV-1 RNA <50 c/mL, Baseline	0	0		
HIV-1 RNA <50 c/mL, Week 4	64	13		
HIV-1 RNA <50 c/mL, Week 12	81	49		
HIV-1 RNA <50 c/mL, Week 24	85	77		
HIV-1 RNA <50 c/mL, Week 36	85	77		
HIV-1 RNA <50 c/mL, Week 48	82	71		
HIV-1 RNA <400 c/mL, Baseline	0.8	0.8		
HIV-1 RNA <400 c/mL, Week 4	90	54		
HIV-1 RNA <400 c/mL, Week 12	91	84		
HIV-1 RNA <400 c/mL, Week 24	88	82		
HIV-1 RNA <400 c/mL, Week 36	86	81		
HIV-1 RNA <400 c/mL, Week 48	83	76		

Notes:

[4] - ITT-E Population

[5] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Plasma HIV-1 RNA at indicated time points

End point title	Change from Baseline in Plasma HIV-1 RNA at indicated time points

End point description:

Change from the Baseline in plasma HIV-1 RNA were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[6]	247[7]		
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Baseline, n=248, 247	4.481 (± 0.8111)	4.441 (± 0.8023)		

Week 4, n=245, 238	-2.646 (± 0.7971)	-1.932 (± 0.5303)		
Week 12, n=236, 226	-2.831 (± 0.8945)	-2.585 (± 0.7321)		
Week 24, n=225, 212	-2.868 (± 0.9196)	-2.801 (± 0.892)		
Week 36, n=221, 204	-2.922 (± 0.8611)	-2.851 (± 0.847)		
Week 48, n=207, 192	-2.96 (± 0.8033)	-2.834 (± 0.8462)		

Notes:

[6] - ITT-E Population

[7] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD4+ cell count at indicated timepoints

End point title	Change from Baseline in CD4+ cell count at indicated timepoints

End point description:

Change from Baseline in cluster of differentiation 4(CD4+) cell count were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[8]	247[9]		
Units: Cells per millimeter cube				
arithmetic mean (standard deviation)				
Baseline, n=248, 247	369.7 (± 225.67)	380.3 (± 223.6)		
Week 4, n=245, 237	94.9 (± 140.02)	73.7 (± 108.15)		
Week 12, n=236, 224	143.8 (± 142.19)	124.4 (± 133.6)		
Week 24, n=226, 210	200.6 (± 162.37)	163 (± 126.67)		
Week 36, n=219, 204	230.7 (± 163.61)	191.4 (± 167.24)		
Week 48, n=208, 191	248.8 (± 172.01)	230.7 (± 189.59)		

Notes:

[8] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in carbon dioxide, electrolytes, lipids, glucose, urea at indicated time points

End point title	Change from Baseline in carbon dioxide, electrolytes, lipids, glucose, urea at indicated time points

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in carbon dioxide, electrolytes (chloride, hyperkalemia, hypernatremia, hypokalemia, hyponatremia, phosphate, potassium, sodium), lipids (cholesterol [CHLS], high density lipoprotein [HDL] CHLS direct, low density lipoprotein (LDL) CHLS calculation, LDL CHLS direct, triglycerides), glucose (hyperglycaemia, hypoglycaemia) and urea are summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Laboratory parameters were assessed in Safety Population which comprised of all participants who received at least one dose of study treatment. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). A value of "99999" indicates where no data is available or not able to determine the value.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[10]	247[11]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Carbon Dioxide, Baseline, n= 248, 247	22.1 (± 2.37)	21.5 (± 2.28)		
Carbon Dioxide, Week 4, n= 244, 237	-0.4 (± 2.29)	0.6 (± 2.2)		
Carbon Dioxide, Week 12, n= 236, 226	-0.2 (± 2.2)	0.8 (± 2.19)		
Carbon Dioxide, Week 24, n= 224, 212	-0.5 (± 2.31)	0.3 (± 2.38)		
Carbon Dioxide, Week 36, n= 219, 204	0 (± 2.34)	0.6 (± 2.5)		
Carbon Dioxide, Week 48, n= 208, 192	-0.6 (± 2.55)	0.4 (± 2.46)		
Chloride, Baseline, n= 248, 247	104 (± 2.49)	104.6 (± 2.63)		
Chloride, Week 4, n= 245, 237	0.6 (± 2.42)	-0.5 (± 2.68)		
Chloride, Week 12, n= 236, 226	1 (± 2.51)	0.2 (± 2.58)		
Chloride, Week 24, n= 225, 212	0.7 (± 2.71)	-0.1 (± 2.58)		
Chloride, Week 36, n= 219, 204	0.9 (± 2.65)	0 (± 2.96)		
Chloride, Week 48, n= 208, 192	0.7 (± 2.42)	0 (± 2.63)		
CHLS, Baseline, n= 230, 232	4.351 (± 0.9389)	4.324 (± 0.9766)		

CHLS, Week 4, n= 1, 3	-0.1 (± 99999)	-0.017 (± 0.446)		
CHLS, Week 12, n= 224, 221	0.298 (± 0.7492)	-0.058 (± 0.7137)		
CHLS, Week 24, n= 218, 201	0.317 (± 0.7254)	-0.001 (± 0.7456)		
CHLS, Week 36, n= 205, 191	0.33 (± 0.7328)	0 (± 0.7509)		
CHLS, Week 48, n= 195, 175	0.447 (± 0.7441)	0.109 (± 0.7647)		
Glucose, Baseline, n= 231, 234	4.91 (± 1.003)	4.88 (± 1.41)		
Glucose, Week 12, n= 226, 224	0.3 (± 1.359)	0.22 (± 1.234)		
Glucose, Week 24, n= 219, 204	0.17 (± 0.811)	0.26 (± 1.248)		
Glucose, Week 36, n= 211, 196	0.17 (± 1.24)	0.34 (± 1.753)		
Glucose, Week 48, n= 197, 180	0.18 (± 1.01)	0.24 (± 1.377)		
HDL CHLS, Direct, Baseline, n= 230, 232	1.23 (± 0.3717)	1.235 (± 0.3953)		
HDL CHLS, Direct, Week 4, n= 1, 3	-0.1 (± 99999)	0 (± 0.0529)		
HDL CHLS, Direct, Week 12, n= 224, 221	0.182 (± 0.3407)	0.005 (± 0.2316)		
HDL CHLS, Direct, Week 24, n= 218, 201	0.201 (± 0.2962)	0.053 (± 0.2819)		
HDL CHLS, Direct, Week 36, n= 205, 191	0.204 (± 0.2943)	0.036 (± 0.2848)		
HDL CHLS, Direct, Week 48, n= 195, 175	0.231 (± 0.2911)	0.081 (± 0.2964)		
Hyperglycaemia, Baseline, n= 231, 234	4.91 (± 1.003)	4.88 (± 1.41)		
Hyperglycaemia, Week 12, n= 226, 224	0.3 (± 1.359)	0.22 (± 1.234)		
Hyperglycaemia, Week 24, n= 219, 204	0.17 (± 0.811)	0.26 (± 1.248)		
Hyperglycaemia, Week 36, n= 211, 196	0.17 (± 1.24)	0.34 (± 1.753)		
Hyperglycaemia, Week 48, n= 197, 180	0.18 (± 1.01)	0.24 (± 1.377)		
Hyperkalemia, Baseline, n= 248, 247	4.11 (± 0.304)	4.08 (± 0.33)		
Hyperkalemia, Week 4, n= 244, 237	-0.01 (± 0.344)	0.12 (± 0.367)		
Hyperkalemia, Week 12, n= 236, 226	0.03 (± 0.355)	0.1 (± 0.39)		
Hyperkalemia, Week 24, n= 224, 212	-0.04 (± 0.339)	0.06 (± 0.372)		
Hyperkalemia, Week 36, n= 219, 204	0.03 (± 0.332)	0.13 (± 0.387)		
Hyperkalemia, Week 48, n= 208, 192	-0.04 (± 0.346)	0.04 (± 0.372)		
Hypernatremia, Baseline, n= 248, 247	137.6 (± 2.25)	137.8 (± 2.48)		
Hypernatremia, Week 4, n= 245, 237	0 (± 2.11)	-0.5 (± 2.4)		
Hypernatremia, Week 12, n= 236, 226	0.7 (± 2.3)	0.1 (± 2.51)		
Hypernatremia, Week 24, n= 225, 212	0.6 (± 2.3)	0.2 (± 2.11)		
Hypernatremia, Week 36, n= 219, 204	0.9 (± 2.32)	0.2 (± 2.5)		
Hypernatremia, Week 48, n= 208, 192	0.6 (± 2.24)	0.5 (± 2.39)		
Hypoglycaemia, Baseline, n= 231, 234	4.91 (± 1.003)	4.88 (± 1.41)		
Hypoglycaemia, Week 12, n= 226, 224	0.3 (± 1.359)	0.22 (± 1.234)		
Hypoglycaemia, Week 24, n= 219, 204	0.17 (± 0.811)	0.26 (± 1.248)		
Hypoglycaemia, Week 36, n= 211, 196	0.17 (± 1.24)	0.34 (± 1.753)		
Hypoglycaemia, Week 48, n= 197, 180	0.18 (± 1.01)	0.24 (± 1.377)		
Hypokalemia, Baseline, n= 248, 247	4.11 (± 0.304)	4.08 (± 0.33)		
Hypokalemia, Week 4, n= 244, 237	-0.01 (± 0.344)	0.12 (± 0.367)		
Hypokalemia, Week 12, n= 236, 226	0.03 (± 0.355)	0.1 (± 0.39)		
Hypokalemia, Week 24, n= 224, 212	-0.04 (± 0.339)	0.06 (± 0.372)		

Hypokalemia, Week 36, n= 219, 204	0.03 (± 0.332)	0.13 (± 0.387)		
Hypokalemia, Week 48, n= 208, 192	-0.04 (± 0.346)	0.04 (± 0.372)		
Hyponatremia, Baseline, n= 248, 247	137.6 (± 2.25)	137.8 (± 2.48)		
Hyponatremia, Week 4, n= 245, 237	0 (± 2.11)	-0.5 (± 2.4)		
Hyponatremia, Week 12, n= 236, 226	0.7 (± 2.3)	0.1 (± 2.51)		
Hyponatremia, Week 24, n= 225, 212	0.6 (± 2.3)	0.2 (± 2.11)		
Hyponatremia, Week 36, n= 219, 204	0.9 (± 2.32)	0.2 (± 2.5)		
Hyponatremia, Week 48, n= 208, 192	0.6 (± 2.24)	0.5 (± 2.39)		
LDL CHLS Calculation, Baseline, n= 229, 231	2.513 (± 0.7912)	2.537 (± 0.8016)		
LDL CHLS Calculation, Week 4, n= 1, 3	0.08 (± 99999)	-0.123 (± 0.5255)		
LDL CHLS Calculation, Week 12, n= 221, 219	0.125 (± 0.6045)	-0.14 (± 0.6114)		
LDL CHLS Calculation, Week 24, n= 213, 201	0.111 (± 0.6209)	-0.111 (± 0.6188)		
LDL CHLS Calculation, Week 36, n= 201, 188	0.112 (± 0.6385)	-0.099 (± 0.6049)		
LDL CHLS Calculation, Week 48, n= 190, 175	0.213 (± 0.6499)	-0.021 (± 0.6227)		
LDL CHLS, Direct, Baseline, n= 13, 7	2.522 (± 0.7586)	2.993 (± 0.7707)		
LDL CHLS, Direct, Week 12, n= 0, 1	99999 (± 99999)	-0.44 (± 99999)		
LDL CHLS, Direct, Week 24, n= 1, 0	-0.64 (± 99999)	99999 (± 99999)		
LDL CHLS, Direct, Week 36, n= 1, 0	-0.23 (± 99999)	99999 (± 99999)		
LDL CHLS, Direct, Week 48, n= 0, 0	99999 (± 99999)	99999 (± 99999)		
Phosphate, Baseline, n= 248, 247	1.15 (± 0.1695)	1.142 (± 0.1732)		
Phosphate, Week 4, n= 245, 237	0 (± 0.1461)	-0.032 (± 0.1726)		
Phosphate, Week 12, n= 236, 226	0.02 (± 0.1694)	0.026 (± 0.1634)		
Phosphate, Week 24, n= 225, 212	0.021 (± 0.1628)	0.026 (± 0.1701)		
Phosphate, Week 36, n= 219, 204	0.029 (± 0.1736)	0.009 (± 0.1675)		
Phosphate, Week 48, n= 208, 192	0.016 (± 0.1736)	0 (± 0.1673)		
Potassium, Baseline, n= 248, 247	4.11 (± 0.304)	4.08 (± 0.33)		
Potassium, Week 4, n= 244, 237	-0.01 (± 0.344)	0.12 (± 0.367)		
Potassium, Week 12, n= 236, 226	0.03 (± 0.355)	0.1 (± 0.39)		
Potassium, Week 24, n= 224, 212	-0.04 (± 0.339)	0.06 (± 0.372)		
Potassium, Week 36, n= 219, 204	0.03 (± 0.332)	0.13 (± 0.387)		
Potassium, Week 48, n= 208, 192	-0.04 (± 0.346)	0.04 (± 0.372)		
Sodium, Baseline, n= 248, 247	137.6 (± 2.25)	137.8 (± 2.48)		
Sodium, Week 4, n= 245, 237	0 (± 2.11)	-0.5 (± 2.4)		
Sodium, Week 12, n= 236, 226	0.7 (± 2.3)	0.1 (± 2.51)		
Sodium, Week 24, n= 225, 212	0.6 (± 2.3)	0.2 (± 2.11)		
Sodium, Week 36, n= 219, 204	0.9 (± 2.32)	0.2 (± 2.5)		
Sodium, Week 48, n= 208, 192	0.6 (± 2.24)	0.5 (± 2.39)		

Triglycerides, Baseline, n= 230, 232	1.335 (± 0.8261)	1.217 (± 0.6642)		
Triglycerides, Week 4, n= 1, 3	-0.18 (± 99999)	0.237 (± 0.2491)		
Triglycerides, Week 12, n= 224, 221	-0.04 (± 0.6861)	0.167 (± 0.7074)		
Triglycerides, Week 24, n= 218, 201	0.036 (± 0.7108)	0.125 (± 0.6132)		
Triglycerides, Week 36, n= 205, 191	0.037 (± 0.6732)	0.157 (± 0.6785)		
Triglycerides, Week 48, n= 195, 175	0.018 (± 0.8158)	0.107 (± 0.5527)		
Urea, Baseline, n= 248, 247	4.28 (± 1.329)	4.43 (± 1.518)		
Urea, Week 4, n= 245, 237	-0.04 (± 1.085)	0.1 (± 1.313)		
Urea, Week 12, n= 236, 226	0.08 (± 1.097)	0.16 (± 1.409)		
Urea, Week 24, n= 225, 212	0.03 (± 1.187)	0.12 (± 1.283)		
Urea, Week 36, n= 219, 204	0.08 (± 1.236)	-0.03 (± 1.256)		
Urea, Week 48, n= 208, 192	0.1 (± 1.162)	0.02 (± 1.179)		

Notes:

[10] - Safety population

[11] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in bilirubin and creatinine at indicated timepoints

End point title	Change from Baseline in bilirubin and creatinine at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in bilirubin and creatinine are summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[12]	247[13]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Baseline, n= 248, 247	7.4 (± 3.2)	7.5 (± 3.11)		
Bilirubin, Week 4, n= 244, 237	-0.8 (± 2.59)	27.2 (± 23.15)		
Bilirubin, Week 12, n= 236, 226	-0.6 (± 2.65)	22.8 (± 16.49)		
Bilirubin, Week 24, n= 225, 212	-0.2 (± 3.06)	25 (± 18.38)		

Bilirubin, Week 36, n= 219, 204	-0.2 (± 3.01)	23.8 (± 16.31)		
Bilirubin, Week 48, n= 208, 192	-0.3 (± 3.08)	23.7 (± 17)		
Creatinine, Baseline, n= 248, 247	58.29 (± 12.035)	61.56 (± 15.43)		
Creatinine, Week 4, n= 245, 237	8.4 (± 7.057)	4.89 (± 7.109)		
Creatinine, Week 12, n= 236, 226	9.2 (± 8.288)	5.83 (± 8.357)		
Creatinine, Week 24, n= 225, 212	9.16 (± 9.983)	5.8 (± 8.063)		
Creatinine, Week 36, n= 219, 204	10.08 (± 10.473)	5.37 (± 9.013)		
Creatinine, Week 48, n= 208, 192	9.29 (± 8.614)	5.86 (± 10.252)		

Notes:

[12] - Safety population

[13] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in albumin at indicated timepoints

End point title	Change from Baseline in albumin at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in albumin is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[14]	247[15]		
Units: grams per liter				
arithmetic mean (standard deviation)				
Baseline, n= 248, 247	41.3 (± 4.39)	41.5 (± 3.88)		
Week 4, n= 245, 237	0.1 (± 2.36)	-0.5 (± 2.59)		
Week 12, n= 236, 226	0.5 (± 2.95)	0.1 (± 2.59)		
Week 24, n= 225, 212	1.4 (± 3.2)	0.8 (± 2.95)		
Week 36, n= 219, 204	1.4 (± 3.09)	0.6 (± 2.96)		
Week 48, n= 208, 192	1.7 (± 3.17)	1.3 (± 3.04)		

Notes:

[14] - Safety Population

[15] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatine kinase at indicated time points

End point title	Change from Baseline in alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatine kinase at indicated time points

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatine kinase is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[16]	247[17]		
Units: International units per liter				
arithmetic mean (standard deviation)				
Alanine aminotransferase, Baseline, n= 248, 247	22.5 (± 26.69)	22.3 (± 20.47)		
Alanine aminotransferase, Week 4, n= 245, 237	-3.3 (± 27.54)	-3.4 (± 15.86)		
Alanine aminotransferase, Week 12, n= 236, 226	-5.2 (± 27.51)	-2.3 (± 20.26)		
Alanine aminotransferase, Week 24, n= 225, 212	-5.4 (± 27.92)	-3.7 (± 20.7)		
Alanine aminotransferase, Week 36, n= 219, 204	-4.9 (± 36.11)	-5.3 (± 20.08)		
Alanine aminotransferase, Week 48, n= 208, 192	-5.7 (± 28.54)	-1.5 (± 31.53)		
Alkaline phosphatase, Baseline, n= 248, 247	72.7 (± 22.75)	72 (± 30.26)		
Alkaline phosphatase, Week 4, n= 245, 237	-1.5 (± 14.56)	9.4 (± 28.69)		
Alkaline phosphatase, Week 12, n= 236, 226	-2.1 (± 17.1)	15.1 (± 30.82)		
Alkaline phosphatase, Week 24, n= 225, 212	0.5 (± 17.86)	22.4 (± 41.59)		
Alkaline phosphatase, Week 36, n= 219, 204	0.6 (± 19.19)	20.4 (± 30.7)		
Alkaline phosphatase, Week 48, n= 208, 192	2.9 (± 28.05)	21.9 (± 25.35)		
Aspartate aminotransferase, Baseline, n= 248, 247	28.7 (± 22.11)	28.3 (± 19.77)		
Aspartate aminotransferase, Week 4, n= 244, 237	-3.3 (± 29.8)	-3.6 (± 18.83)		
Aspartate aminotransferase, Week 12, n= 236, 226	-6.2 (± 21.11)	-4 (± 13.79)		

Aspartate aminotransferase, Week 24, n= 224, 212	-6.3 (± 22.44)	-5.1 (± 13.8)		
Aspartate aminotransferase, Week 36, n= 219, 204	-6.4 (± 31.42)	-6.5 (± 16.63)		
Aspartate aminotransferase, Week 48, n= 208, 192	-7.5 (± 22.19)	-3.7 (± 25.28)		
Creatine Kinase, Baseline, n= 248, 247	97.4 (± 88.55)	105.5 (± 100.51)		
Creatine Kinase, Week 4, n= 245, 237	-0.3 (± 68.72)	35.6 (± 549.1)		
Creatine Kinase, Week 12, n= 236, 226	6.9 (± 73.7)	7.3 (± 90.39)		
Creatine Kinase, Week 24, n= 225, 212	10.3 (± 88.66)	5.8 (± 77.12)		
Creatine Kinase, Week 36, n= 219, 204	11.9 (± 155.68)	7.2 (± 132.74)		
Creatine Kinase, Week 48, n= 208, 192	23.8 (± 242.66)	3.8 (± 98.58)		

Notes:

[16] - Safety population

[17] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in creatinine clearance at indicated time points

End point title	Change from Baseline in creatinine clearance at indicated time points

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in creatinine clearance is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[18]	247[19]		
Units: Milliliter per minute				
arithmetic mean (standard deviation)				
Baseline, n= 248, 247	132.1 (± 42.95)	128.7 (± 45.96)		
Week 4, n= 245, 237	-16.3 (± 15.03)	-7.5 (± 12.91)		
Week 12, n= 236, 226	-17.3 (± 17.01)	-7 (± 23.14)		
Week 24, n= 225, 212	-16.2 (± 20.36)	-9.1 (± 16.88)		
Week 36, n= 219, 204	-16.8 (± 22.35)	-7.5 (± 17.67)		

Week 48, n= 208, 192	-15.9 (± 19.62)	-7.7 (± 18.42)		

Notes:

[18] - Safety population

[19] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in lipase at indicated timepoints

End point title	Change from Baseline in lipase at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in lipase is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[20]	247[21]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Baseline, n= 248, 247	32.9 (± 24.67)	32.3 (± 22.14)		
Week 4, n= 245, 237	-1.2 (± 15.06)	-1.3 (± 15.81)		
Week 12, n= 236, 226	-2.2 (± 22.74)	-2.1 (± 29)		
Week 24, n= 225, 212	-6 (± 21.05)	-6 (± 18.57)		
Week 36, n= 219, 204	-6.3 (± 25.62)	-6.3 (± 21.36)		
Week 48, n= 208, 192	-6.5 (± 29.63)	-7.8 (± 20.72)		

Notes:

[20] - Safety Population

[21] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in total CHLS/HDL CHLS ratio at indicated timepoints

End point title	Change from Baseline in total CHLS/HDL CHLS ratio at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48.

Change from Baseline in Total CHLS/HDL CHLS ratio is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). A value of "99999" indicates where no data is available or not able to determine the value.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[22]	247[23]		
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline, n= 247, 245	3.78841 (± 1.33327)	3.84622 (± 2.6556)		
Week 4, n= 1, 4	0.1264 (± 99999)	0.21588 (± 0.60727)		
Week 12, n= 233, 223	-0.2736 (± 1.0283)	-0.1092 (± 0.73776)		
Week 24, n= 224, 209	-0.3098 (± 1.11093)	-0.1922 (± 0.79848)		
Week 36, n= 212, 198	-0.3286 (± 1.01181)	-0.1433 (± 0.79498)		
Week 48, n= 207, 186	-0.2886 (± 1.01415)	-0.1444 (± 1.23362)		

Notes:

[22] - Safety population

[23] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in basophils, eosinophils, lymphocytes, monocytes at indicated time points

End point title	Change from Baseline in basophils, eosinophils, lymphocytes, monocytes at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in basophils, eosinophils, lymphocytes, monocytes are summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[24]	247[25]		
Units: 10^9 per liter				
arithmetic mean (standard deviation)				
Basophils, Baseline, n= 248, 247	0.017 (± 0.0139)	0.017 (± 0.0127)		
Basophils, Week 4, n= 241, 234	0.003 (± 0.0182)	0.003 (± 0.0198)		
Basophils, Week 12, n= 228, 216	0.002 (± 0.0174)	0.003 (± 0.0162)		
Basophils, Week 24, n= 221, 208	0.004 (± 0.0187)	0.003 (± 0.0155)		
Basophils, Week 36, n= 214, 203	0.004 (± 0.0182)	0.003 (± 0.0158)		
Basophils, Week 48, n= 206, 189	0.005 (± 0.0199)	0.006 (± 0.0146)		
Eosinophils, Baseline, n= 248, 247	0.139 (± 0.179)	0.146 (± 0.258)		
Eosinophils, Week 4, n= 241, 234	0.04 (± 0.1486)	0.021 (± 0.1648)		
Eosinophils, Week 12, n= 228, 216	0.037 (± 0.1982)	-0.001 (± 0.161)		
Eosinophils, Week 24, n= 221, 208	0.028 (± 0.1927)	0.005 (± 0.1973)		
Eosinophils, Week 36, n= 214, 203	0.048 (± 0.2244)	0.014 (± 0.2139)		
Eosinophils, Week 48, n= 206, 189	0.03 (± 0.1744)	0.007 (± 0.2274)		
Lymphocytes, Baseline, n= 248, 247	1.538 (± 0.6092)	1.573 (± 0.7895)		
Lymphocytes, Week 4, n= 241, 234	0.208 (± 0.4914)	0.119 (± 0.5493)		
Lymphocytes, Week 12, n= 228, 216	0.257 (± 0.55)	0.156 (± 0.669)		
Lymphocytes, Week 24, n= 221, 208	0.317 (± 0.4889)	0.192 (± 0.591)		
Lymphocytes, Week 36, n= 214, 203	0.362 (± 0.5199)	0.178 (± 0.6441)		
Lymphocytes, Week 48, n= 206, 189	0.359 (± 0.5235)	0.261 (± 0.7098)		
Monocytes, Baseline, n= 248, 247	0.315 (± 0.1491)	0.326 (± 0.1606)		
Monocytes, Week 4, n= 241, 234	-0.001 (± 0.1558)	-0.015 (± 0.1391)		
Monocytes, Week 12, n= 228, 216	-0.01 (± 0.1412)	-0.031 (± 0.1369)		
Monocytes, Week 24, n= 221, 208	0.008 (± 0.1498)	-0.015 (± 0.1581)		
Monocytes, Week 36, n= 214, 203	-0.006 (± 0.1448)	-0.028 (± 0.15)		
Monocytes, Week 48, n= 206, 189	0.001 (± 0.1379)	-0.024 (± 0.1638)		

Notes:

[24] - Safety population

[25] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in erythrocytes at indicated time points

End point title	Change from Baseline in erythrocytes at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in erythrocytes is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[26]	247[27]		
Units: 10^12 per liter				
arithmetic mean (standard deviation)				
Baseline, n= 248, 247	4.27 (± 0.467)	4.28 (± 0.44)		
Week 4, n= 243, 234	-0.04 (± 0.244)	-0.07 (± 0.239)		
Week 12, n= 233, 220	-0.07 (± 0.351)	-0.09 (± 0.308)		
Week 24, n= 225, 211	-0.08 (± 0.373)	-0.09 (± 0.329)		
Week 36, n= 218, 203	-0.1 (± 0.384)	-0.08 (± 0.358)		
Week 48, n= 207, 190	-0.1 (± 0.365)	-0.05 (± 0.318)		

Notes:

[26] - Safety population

[27] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematocrit count at indicated time points

End point title	Change from Baseline in hematocrit count at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in hematocrit is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[28]	247[29]		
Units: Fraction of 1				
arithmetic mean (standard deviation)				
Baseline, n= 248, 247	0.3757 (± 0.03978)	0.3766 (± 0.03675)		
Week 4, n= 243, 234	0.0003 (± 0.02176)	-0.0042 (± 0.02238)		
Week 12, n= 233, 220	0.0081 (± 0.03157)	0 (± 0.02646)		
Week 24, n= 225, 211	0.0157 (± 0.03209)	0.0051 (± 0.03083)		
Week 36, n= 218, 203	0.0167 (± 0.03451)	0.0062 (± 0.03379)		
Week 48, n= 207, 190	0.0212 (± 0.03293)	0.0107 (± 0.032)		

Notes:

[28] - Safety population

[29] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in erythrocyte mean corpuscular volume at indicated time points

End point title	Change from Baseline in erythrocyte mean corpuscular volume at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in erythrocyte mean corpuscular volume (EMCV) is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24, 36, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[30]	247[31]		
Units: Femtoliter				
arithmetic mean (standard deviation)				
Baseline, n= 248, 247	88.4 (± 6.45)	88.4 (± 7.01)		
Week 4, n= 243, 234	0.9 (± 1.81)	0.5 (± 1.83)		
Week 12, n= 233, 220	3.4 (± 2.98)	1.9 (± 2.94)		
Week 24, n= 225, 211	5.5 (± 4.03)	3.1 (± 4.33)		
Week 36, n= 218, 203	6 (± 4.04)	3.1 (± 5.22)		
Week 48, n= 207, 190	7.1 (± 4.31)	3.7 (± 5.15)		

Notes:

[30] - Safety population

[31] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Triglycerides at Week 48

End point title	Change from Baseline in Triglycerides at Week 48

End point description:

Change from Baseline in mean triglycerides is summarized at Week 48. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Adjusted mean is the estimated mean change from Baseline in fasted triglycerides at Week 48 in each arm calculated from a model adjusted for the following covariates: treatment, Baseline plasma HIV-1 RNA, Baseline CD4+ cell count, age and triglycerides at Baseline. Subjects on lipid lowering therapy at baseline were excluded from analysis. Measurements collected after a subject initiates lipid lowering therapy were set to missing. Missing values were imputed using multiple imputation under a multivariate normal model adjusting for Baseline plasma HIV-1 RNA, Baseline CD4+ cell count, fasted triglycerides and TC/HDL ratio at Baseline, Week 12 and Week 36.

End point type	Secondary

End point timeframe:

Baseline and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226[32]	214[33]		
Units: Millimoles per liter				
least squares mean (standard error)	0.045 (± 0.0477)	0.07 (± 0.0477)		

Notes:

[32] - Safety population

[33] - Safety population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	440
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7053
Method	Multiple Imputed Dataset - MAR
Parameter estimate	Mean difference (final values)
Point estimate	-0.026
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.159
upper limit	0.107

Secondary: Change from Baseline in TC/HDL Ratio at Week 48

End point title	Change from Baseline in TC/HDL Ratio at Week 48

End point description:

Change from Baseline in mean total cholesterol (TC)/HDL ratio is summarized at Week 48. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Adjusted mean is the estimated mean change from Baseline in fasted TC/HDL at Week 48 in each arm calculated from a model adjusted for the following covariates: treatment, Baseline plasma HIV-1 RNA, Baseline CD4+ cell count, age and triglycerides/HDL at Baseline. Subjects on lipid lowering therapy at baseline were excluded from analysis. Measurements collected after a subject initiates lipid lowering therapy were set to missing. Missing values were imputed using multiple imputation under a multivariate normal model adjusting for Baseline plasma HIV-1 RNA, Baseline CD4+ cell count, fasted triglycerides and TC/HDL ratio at Baseline, Week 12 and Week 36.

End point type	Secondary

End point timeframe:

Baseline and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226[34]	214[35]		
Units: Ratio				
arithmetic mean (standard deviation)	-0.264 (± 0.0707)	-0.158 (± 0.0784)		

Notes:

[34] - Safety population

[35] - Safety population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	440
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3165
Method	Multiple Imputed Dataset - MAR
Parameter estimate	Mean difference (final values)
Point estimate	-0.106
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.313
upper limit	0.101

Secondary: Change from Baseline in urine albumin creatinine ratio at indicated time points

End point title	Change from Baseline in urine albumin creatinine ratio at indicated time points

End point description:

Change from Baseline in urine albumin creatinine ratio at Week 24 and Week 48 are summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 24, Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[36]	247[37]		
Units: milligrams per millimole				
arithmetic mean (standard deviation)				
Baseline, n= 221, 231	5.69 (± 27.277)	3.44 (± 8.52)		
Week 24, n= 179, 186	-1.15 (± 16.557)	-1.03 (± 9.091)		
Week 48, n= 170, 164	-0.68 (± 20.597)	-0.1 (± 9.393)		

Notes:

[36] - Safety population

[37] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of AE's by maximum toxicity as per DAIDS AE Grading Table

End point title	Summary of AE's by maximum toxicity as per DAIDS AE Grading Table

End point description:

Number of participants with Grade 1-4 AEs were assessed from the start of study treatment and until end of the Randomization phase. AEs are categorized into following grades as per The Division of Acquired Immuno Deficiency Syndrome (AIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe Grade 4- potentially life-threatening.

End point type	Secondary

End point timeframe:

Average of 354 days for DTG/ABC/3TC, and average of 336 days for ATV+RTV+TDF/FTC

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[38]	247[39]		
Units: Participants				
number (not applicable)				
Grade 1	79	60		
Grade 2	94	91		
Grade 3	18	37		
Grade 4	3	9		

Notes:

[38] - Safety population

[39] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any adverse events (AEs), and serious adverse events (SAEs)

End point title	Number of participants with any adverse events (AEs), and serious adverse events (SAEs)

End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. A serious adverse event (SAE) is any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect or other events that may jeopardize the participant or may require medical or surgical intervention to prevent one of the outcome listed above, liver injury and impaired liver function and grade 4 laboratory abnormalities. Number of participants with any AEs, and SAEs have been presented.

End point type	Secondary

End point timeframe:

From start of IP through the Study Phase (average of 354 days for DTG/ABC/3TC, and average of 336 days for ATV+RTV+TDF/FTC)

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[40]	247[41]		
Units: Participants				
number (not applicable)				
Any AEs	132	160		
Any SAEs	16	20		

Notes:

[40] - Safety population

[41] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of maximum post-Baseline emergent chemistry toxicities

End point title	Summary of maximum post-Baseline emergent chemistry toxicities

End point description:

Number of participants with Grade 1-4 emergent chemistry toxicities were assessed from the start of study treatment and until the follow up contact. Chemistry toxicities were categorized into following grades as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe Grade 4- potentially life-threatening.

End point type	Secondary

End point timeframe:

Average of 354 days for DTG/ABC/3TC, and average of 336 days for ATV+RTV+TDF/FTC

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[42]	247[43]		
Units: Participants				
number (not applicable)				
Hyperglycaemia, Grade 1	23	15		
Hyperglycaemia, Grade 2	21	15		
Hyperglycaemia, Grade 3	4	3		
Hyperglycaemia, Grade 4	1	0		
Hyperkalemia, Grade 1	1	0		
Hyperkalemia, Grade 2	0	1		
Hyperkalemia, Grade 3	0	0		
Hyperkalemia, Grade 4	0	0		

Hypernatremia, Grade 1	1	0		
Hypernatremia, Grade 2	0	0		
Hypernatremia, Grade 3	0	0		
Hypernatremia, Grade 4	0	0		
Hypoglycaemia, Grade 1	9	7		
Hypoglycaemia, Grade 2	4	1		
Hypoglycaemia, Grade 3	1	0		
Hypoglycaemia, Grade 4	0	0		
Hypokalemia, Grade 1	18	21		
Hypokalemia, Grade 2	1	0		
Hypokalemia, Grade 3	0	0		
Hypokalemia, Grade 4	0	0		
Hyponatremia, Grade 1	79	82		
Hyponatremia, Grade 2	1	0		
Hyponatremia, Grade 3	0	0		
Hyponatremia, Grade 4	0	0		
Alanine aminotransferase, Grade 1	7	11		
Alanine aminotransferase, Grade 2	8	5		
Alanine aminotransferase, Grade 3	1	2		
Alanine aminotransferase, Grade 4	1	0		
Albumin, Grade 1	6	2		
Albumin, Grade 2	1	4		
Albumin, Grade 3	0	0		
Albumin, Grade 4	0	0		
Alkaline phosphatase, Grade 1	4	17		
Alkaline phosphatase, Grade 2	2	1		
Alkaline phosphatase, Grade 3	0	0		
Alkaline phosphatase, Grade 4	0	0		
Aspartate aminotransferase, Grade 1	17	14		
Aspartate aminotransferase, Grade 2	8	5		
Aspartate aminotransferase, Grade 3	1	2		
Aspartate aminotransferase, Grade 4	1	0		
Bilirubin, Grade 1	2	52		
Bilirubin, Grade 2	0	86		
Bilirubin, Grade 3	0	57		
Bilirubin, Grade 4	0	5		
Carbon dioxide, Grade 1	94	74		
Carbon dioxide, Grade 2	5	4		
Carbon dioxide, Grade 3	0	0		
Carbon dioxide, Grade 4	0	0		
Cholesterol, Grade 1	74	47		
Cholesterol, Grade 2	32	13		
Cholesterol, Grade 3	4	2		
Cholesterol, Grade 4	0	0		
Creatine kinase, Grade 1	4	7		
Creatine kinase, Grade 2	1	1		
Creatine kinase, Grade 3	4	0		
Creatine kinase, Grade 4	0	1		
Creatinine, Grade 1	5	8		
Creatinine, Grade 2	0	3		
Creatinine, Grade 3	1	0		
Creatinine, Grade 4	0	0		

LDL cholesterol calculation, Grade 1	53	31		
LDL cholesterol calculation, Grade 2	15	11		
LDL cholesterol calculation, Grade 3	7	3		
LDL cholesterol calculation, Grade 4	0	0		
LDL cholesterol direct, Grade 1	3	1		
LDL cholesterol direct, Grade 2	1	0		
LDL cholesterol direct, Grade 3	0	0		
LDL cholesterol direct, Grade 4	0	0		
Lipase, Grade 1	16	11		
Lipase, Grade 2	11	5		
Lipase, Grade 3	3	2		
Lipase, Grade 4	0	1		
Phosphate, Grade 1	5	12		
Phosphate, Grade 2	9	13		
Phosphate, Grade 3	1	2		
Phosphate, Grade 4	0	0		
Potassium, Grade 1	19	21		
Potassium, Grade 2	1	1		
Potassium, Grade 3	0	0		
Potassium, Grade 4	0	0		
Sodium, Grade 1	80	82		
Sodium, Grade 2	1	0		
Sodium, Grade 3	0	0		
Sodium, Grade 4	0	0		
Triglycerides, Grade 1	0	0		
Triglycerides, Grade 2	5	2		
Triglycerides, Grade 3	2	0		
Triglycerides, Grade 4	0	0		
Glucose, Grade 1	28	21		
Glucose, Grade 2	24	14		
Glucose, Grade 3	4	3		
Glucose, Grade 4	1	0		

Notes:

[42] - Safety population

[43] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of maximum post-Baseline emergent hematology toxicities

End point title	Summary of maximum post-Baseline emergent hematology toxicities

End point description:

Number of participants with Grade 1-4 emergent hematology toxicities were assessed from the start of study treatment and until the follow up contact. Hematology toxicities were categorized into following grades as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe Grade 4- potentially life-threatening.

End point type	Secondary

End point timeframe:

Average of 354 days for DTG/ABC/3TC, and average of 336 days for ATV+RTV+TDF/FTC

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[44]	247[45]		
Units: Participants				
number (not applicable)				
Hemoglobin, Grade 1	21	30		
Hemoglobin, Grade 2	4	3		
Hemoglobin, Grade 3	1	1		
Hemoglobin, Grade 4	0	0		
Leukocytes, Grade 1	6	6		
Leukocytes, Grade 2	1	2		
Leukocytes, Grade 3	0	0		
Leukocytes, Grade 4	0	0		
Neutrophils, Grade 1	19	14		
Neutrophils, Grade 2	7	9		
Neutrophils, Grade 3	0	3		
Neutrophils, Grade 4	1	1		
Platelets, Grade 1	9	1		
Platelets, Grade 2	0	4		
Platelets, Grade 3	1	0		
Platelets, Grade 4	0	0		

Notes:

[44] - Safety population

[45] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who withdrew from treatment due to AEs

End point title	Number of participants who withdrew from treatment due to AEs

End point description:

An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product (MP), whether or not considered related to the MP. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of an MP. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, is an important medical event that jeopardizes the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition, or is associated with liver injury and impaired liver function.

End point type	Secondary

End point timeframe:

Average of 354 days for DTG/ABC/3TC, and average of 336 days for ATV+RTV+TDF/FTC

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[46]	247[47]		
Units: Participants				
number (not applicable)	11	17		

Notes:

[46] - Safety population

[47] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in bone specific alkaline phosphatase, osteocalcin and procollagen 1 N-terminal propeptide at indicated timepoints

End point title	Change from Baseline in bone specific alkaline phosphatase, osteocalcin and procollagen 1 N-terminal propeptide at indicated timepoints

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Change from Baseline in bone specific alkaline phosphatase (BSAP), osteocalcin and procollagen 1 N-terminal propeptide (PTP) is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. A value of "99999" indicates where no data is available or not able to determine the value. Only those participants available at the specified time points (represented by n=X, X in the category titles) were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 24, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[48]	247[49]		
Units: Micrograms per liter				
arithmetic mean (standard deviation)				
BSAP, Baseline, n=244, 243	11.52 (± 3.837)	11.67 (± 5.287)		
BSAP, Week 24, n=219, 207	1.33 (± 3.934)	6 (± 5.962)		
BSAP, Week 48, n=202, 184	2.64 (± 5.746)	7.6 (± 7.144)		
Osteocalcin, Baseline, n=235, 235	16.6 (± 8.551)	18.27 (± 19.891)		
Osteocalcin, Week 24, n=209, 197	3.73 (± 7.484)	14.38 (± 22.205)		

Osteocalcin, Week 48, n=194, 178	5.15 (± 9.018)	16.3 (± 25.043)		
PTP, Baseline, n=246, 240	49.4 (± 24.48)	49.5 (± 23.01)		
PTP, Week 24, n=223, 206	10.1 (± 20.11)	32 (± 27.89)		
PTP, Week 48, n=205, 186	11.2 (± 23.05)	34.1 (± 27.28)		

Notes:

[48] - Safety population

[49] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Type I collagen C-telopeptides at indicated timepoints

End point title	Change from Baseline in Type I collagen C-telopeptides at indicated timepoints

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Change from Baseline in Type I collagen C-telopeptides (T-1 CCT) is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. A value of "99999" indicates where no data is available or not able to determine the value. Only those participants available at the specified time points (represented by n=X, X in the category titles) were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 24, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[50]	247[51]		
Units: Nanograms per liter				
arithmetic mean (standard deviation)				
Baseline, n=245, 243	312.9 (± 183.68)	329.7 (± 190.02)		
Week 24, n=221, 207	89.8 (± 173.09)	272.4 (± 205.22)		
Week 48, n=202, 185	75.9 (± 173.73)	267.9 (± 200.82)		

Notes:

[50] - Safety population

[51] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in vitamin D, vitamin D2 and vitamin D3 at Week 24 and Week 48

End point title	Change from Baseline in vitamin D, vitamin D2 and vitamin D3

	at Week 24 and Week 48

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Change from Baseline in vitamin D and vitamin D2 is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points (represented by n=X, X in the category titles) were analyzed. A value of "99999" indicates where no data is available or not able to determine the value.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[52]	247[53]		
Units: Nanomoles per liter				
arithmetic mean (standard deviation)				
Vitamin D, Baseline, n=247, 244	58.6 (± 30.15)	56.9 (± 22.43)		
Vitamin D, Week 24, n=223, 208	1.8 (± 24.95)	16.3 (± 31.66)		
Vitamin D, Week 48, n=206, 186	-1.9 (± 20.63)	8.9 (± 23.78)		
Vitamin D2, Baseline, n=247, 244	9.3 (± 3.16)	9.5 (± 3.79)		
Vitamin D2, Week 24, n=223, 208	0.3 (± 6.04)	1 (± 7.88)		
Vitamin D2, Week 48, n=206, 186	0.1 (± 4.71)	0.9 (± 11)		
Vitamin D3, Baseline, n=247, 244	58.1 (± 30.07)	56.1 (± 22.59)		
Vitamin D3, Week 24, n=223, 208	1.5 (± 24.33)	15.2 (± 31.39)		
Vitamin D3, Week 48, n=206, 186	-1.9 (± 20.56)	7.9 (± 21.72)		

Notes:

[52] - Safety population

[53] - Safety population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline at Week 48 in SF-12 Total Score, MCS and PCS

End point title	Change from Baseline at Week 48 in SF-12 Total Score, MCS and PCS

End point description:

The SF-12 is the 12 item abbreviated form of SF-36 survey. It provides information about how participants feel, and how well they have been able to perform their usual activities. SF-12 questions make up 8 scales: Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, Mental Health . Transformed physical component summary score (PCS) and transformed mental component summary score (MCS) are derived using all the 12 items and scored onto a 0-100 scale such that a higher score indicates a better health state and better functioning. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants available at the specified time points (represented by n=X, X in the category titles) were analyzed.

End point type	Secondary

End point timeframe:

Baseline and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[54]	247[55]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Total Score, Baseline, n=245, 240	38.6 (± 4.33)	38.5 (± 4.47)		
Total Score, Week 48, n=205, 192	0 (± 5.15)	0.1 (± 5.66)		
MCS, Baseline, n=245, 240	48.31 (± 10.3025)	47.67 (± 10.4284)		
MCS, Week 48, n=205, 192	2.397 (± 10.5232)	2.329 (± 9.9782)		
PCS, Baseline, n=245, 240	50.663 (± 8.4227)	50.374 (± 8.0038)		
PCS, Week 48, n=205, 192	1.905 (± 8.6309)	1.444 (± 8.3938)		

Notes:

[54] - ITT-E population

[55] - ITT-E population

Statistical analyses

No statistical analyses for this end point

Secondary: Assessment of HIVTSQs Total Score at indicated timepoints.

End point title	Assessment of HIVTSQs Total Score at indicated timepoints.

End point description:

The HIV treatment satisfaction questionnaire (HIVTSQ) is a 10-item self-reported scale that measures overall satisfaction with treatment and by specific domains e.g. convenience, flexibility. The HIVTSQ items are summed up to produce a treatment satisfaction score (0 to 60) and an individual satisfaction rating for each item (0 to 6) and two subscales: general satisfaction/clinical and lifestyle/ease subscales. The higher the score, the greater the improvement in treatment satisfaction as compared to the past few weeks. A smaller score represents a decline in treatment satisfaction compared to the past few weeks. Statistical analysis was performed based on Wilcoxon rank sum test. Only those participants available at the specified time points (represented by n=X, X in the category titles) were analyzed.

End point type	Secondary

End point timeframe:

Week 4, 12, 24, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[56]	247[57]		
Units: Score on a scale				
arithmetic mean (standard deviation)				

Week 4, n=243, 239	54 (± 6.37)	51.9 (± 8.53)		
Week 12, n=236, 226	56.1 (± 5.38)	53.6 (± 7.67)		
Week 24, n=225, 211	56.8 (± 4.55)	54.3 (± 7.27)		
Week 48, n=206, 191	57 (± 4.38)	55.4 (± 6)		

Notes:

[56] - ITT-E population

[57] - ITT-E population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Comparison of HIV treatment satisfaction questionnaire (HIVTSQ) between two groups at week 4	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.016 [58]
Method	Wilcoxon (Mann-Whitney)

Notes:

[58] - Week 4

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Comparison of HIV treatment satisfaction questionnaire (HIVTSQ) between two groups at week 12	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001 [59]
Method	Wilcoxon (Mann-Whitney)

Notes:

[59] - Week 12

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Comparison of HIV treatment satisfaction questionnaire (HIVTSQ) between two groups at week 24	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002 [60]
Method	Wilcoxon (Mann-Whitney)

Notes:

[60] - Week 24

Statistical analysis title	Statistical analysis 4

Statistical analysis description:	
Comparison of HIV treatment satisfaction questionnaire (HIVTSQ) between two groups at week 48	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.007 [61]
Method	Wilcoxon (Mann-Whitney)

Notes:

[61] - Week 48

Secondary: Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 by subgroups

End point title	Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 by subgroups

End point description:

Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 by subgroups (age, race, country, Baseline plasma HIV-1 RNA (BPHR), Baseline CD4+ cell count (BCCC), Baseline Centers for Disease Control and Prevention (CDC) category and HIV-1 subtype) were assessed using the Snapshot algorithm (Missing, Switch or Discontinuation = Failure). Analysis was performed using a stratified analysis with CMH weights, adjusting for Baseline plasma HIV-1 RNA (=<vs. >100,000 c/mL) and CD4+ cell count (=<350 cells/mm^3 or >350 cells/mm^3). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population.

End point type	Secondary

End point timeframe:

Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[62]	247[63]		
Units: Percentage of Participants				
number (not applicable)				
Age, <50 Years, n=212, 212	80	71		
Age, >=50 Years, n=36, 35	92	74		
Race, White, n=115, 107	86	80		
Race, Non-White, n=133,140	78	64		
Race, African-American/African Heritage, n=102,108	74	67		
Non-African-American/African Heritage, n=146, 139	88	75		
BPHR, <1000, n=5, 10	60	80		
BPHR, 1000 to <10,000, n=66, 62	83	77		
BPHR, 10,000 to <50,000, n=83, 81	84	74		
BPHR, 50,000 to <=100,000, n=25, 28	80	64		
BPHR, >100,000, n=69, 66	80	64		
BCCC, <200, n=64, 49	81	69		
BCCC, >=200, n=184, 198	82	72		

BCCC, <50, n=9, 15	67	60		
BCCC, 50 to <200, n=55, 34	84	74		
BCCC, 200 to <350, n=66, 74	89	73		
BCCC, 350 to <500, n=56, 65	79	74		
BCCC, >=500, n=62, 59	77	68		
CDC category, A, n=210, 208	81	71		
CDC category, B, n=27, 30	81	77		
CDC category, C, n=11, 9	91	56		
HIV-1 subtype: B vs Non-B, B, n=95, 111	80	69		
IV-1 subtype: B vs Non-B, non-B, n=140, 131	84	73		

Notes:

[62] - ITT-E Population

[63] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with post-Baseline HIV-1disease progression

End point title	Number of participants with post-Baseline HIV-1disease progression

End point description:

Number of participants with post-Baseline HIV-1disease progression were assessed during study period. The CDC Classification System for HIV Infection is the medical classification system used by the United States Centers for Disease Control and Prevention (CDC) to classify HIV disease and infection. The clinical categories of HIV infection are defined as follows: Category A: Mildly symptomatic, Category B: Moderately symptomatic, Category C: Severely symptomatic. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Only those participants available at the specified time points were analyzed. Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[64]	7[65]		
Units: Participants				
number (not applicable)				
CDC Class A to CDC Class C	5	4		
CDC Class B to CDC Class C	1	2		
CDC Class C to new CDC Class C	0	0		
CDC Class A, B or C to Death	1	1		

Notes:

[64] - ITT-E Population

[65] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with treatment emergent resistances

End point title	Number of Participants with treatment emergent resistances

End point description:

Number of participants, who met confirmed virologic withdrawal criteria, with treatment emergent genotypic resistance to INI, NNRTI, NRTI, PI are summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. On-treatment Genotypic Resistance Population comprised of all participants in the ITT-E population with available On-treatment genotypic resistance data at the time confirmed virologic withdrawal criterion was met.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[66]	4[67]		
Units: Participants				
number (not applicable)				
Any mutation	0	1		
INSTI	0	0		
NRTI	0	1		
M184M/I/V	0	1		
PI	0	1		

Notes:

[66] - On-treatment Genotypic Resistance Population

[67] - On-treatment Genotypic Resistance Population

Statistical analyses

No statistical analyses for this end point

Post-hoc: Bone specific alkaline phosphatase, osteocalcin, procollagen 1 N-terminal propeptide, Type 1 Collagen C-Telopeptide, vitamin D ratio of Week 48 results over Baseline

End point title	Bone specific alkaline phosphatase, osteocalcin, procollagen 1 N-terminal propeptide, Type 1 Collagen C-Telopeptide, vitamin D ratio of Week 48 results over Baseline

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Bone specific alkaline phosphatase (BSAP), osteocalcin and procollagen 1 N-terminal propeptide (PTP), Type 1 Collagen C-Telopeptide, vitamin D ratio of Week 48 results over Baseline is calculated. Bone biomarkers were analysed based on log transformed data. Only those participants available at the specified time points (represented by n=X, X in the category titles) were analyzed. Estimates of adjusted mean and difference were calculated from an ANCOVA model adjusting for age, baseline viral load Baseline CD4+ cell count, Baseline biomarker level, body mass index category, smoking status and baseline Vitamin D use. Adjusted mean of log-transformed change from Baseline are transformed back to Week 48/Baseline ratio for each treatment group. Adjusted difference of log-transformed change from Baseline between treatment groups is transformed back to the ratio of Week 48/Baseline ratio in DTG/ABC/3TC FDC to

ATV+RTV+TDF/FTC FDC.

End point type	Post-hoc

End point timeframe:

Baseline, Weeks 24, 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[68]	247[69]		
Units: Ratio				
number (confidence interval 95%)				
BSAP, n=202, 183	1.188 (1.135 to 1.243)	1.629 (1.553 to 1.708)		
PTP, n=202, 184	1.214 (1.158 to 1.272)	1.752 (1.668 to 1.84)		
Osteocalcin, n=194, 178	1.282 (1.214 to 1.354)	2.039 (1.926 to 2.159)		
Type 1 Collagen C-Telopeptide, n=202, 184	1.257 (1.195 to 1.323)	1.918 (1.819 to 2.023)		
Vitamin D, n=206, 186	0.987 (0.94 to 1.036)	1.158 (1.101 to 1.219)		

Notes:

[68] - Safety population

[69] - Safety population

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Comparison of Bone specific alkaline phosphatase (BSAP) ratio between 2 groups

Comparison groups	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD v DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Number of subjects included in analysis	495
Analysis specification	Post-hoc
Analysis type	other[70]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio of ratio
Point estimate	0.729
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.683
upper limit	0.779

Notes:

[70] - BSAP ratio of Week 48 result over Baseline

Statistical analysis title	Statistical analysis 2

Statistical analysis description:	
Comparison of procollagen 1 N-terminal propeptide (PTP) ratio between 2 groups	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Post-hoc
Analysis type	other[71]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio of ratio
Point estimate	0.693
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.647
upper limit	0.741

Notes:

[71] - PTP ratio of Week 48 result over Baseline

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Comparison of Osteocalcin ratio between 2 groups	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Post-hoc
Analysis type	other[72]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio of ratio
Point estimate	0.629
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.581
upper limit	0.68

Notes:

[72] - Osteocalcin ratio of Week 48 result over Baseline

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Comparison of Type 1 Collagen C-Telopeptide ratio between 2 groups	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD v ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD
Number of subjects included in analysis	495
Analysis specification	Post-hoc
Analysis type	other[73]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio of ratio
Point estimate	0.655

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.609
upper limit	0.706

Notes:

[73] - Type 1 Collagen C-Telopeptide ratio of Week 48 result over Baseline

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Comparison of Vitamin D ratio between 2 groups

Comparison groups	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD v DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Number of subjects included in analysis	495
Analysis specification	Post-hoc
Analysis type	other[74]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio of ratio
Point estimate	0.852
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.794
upper limit	0.914

Notes:

[74] - Vitamin D ratio of Week 48 result over Baseline

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs and SAEs were collected from start of study treatment until end of study treatment (average of 354 days for DTG/ABC/3TC, and average of 336 days for ATV+RTV+TDF/FTC)

Adverse event reporting additional description:

On-treatment SAEs and non-serious AEs are reported for the Safety Population, which comprises of all randomized participants who received at least one dose of study treatment. AEs were identified post-hoc for two ATV+RTV+TDF/FTC FDC subjects at one site. These AEs are not included and are not considered to affect the overall safety findings.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD

Reporting group description:

Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants on this arm who successfully completed the Randomized Phase were allowed access to DTG/ABC/3TC FDC in the Continuation Phase until it was i) locally approved and commercially available, or ii) the participant no longer derived clinical benefit or iii) the participant met a protocol-defined reason for discontinuation, or iv) development of DTG/ABC/3TC FDC was discontinued/terminated.

Reporting group title	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD

Reporting group description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks.

Serious adverse events	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD	
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 248 (6.45%)	20 / 247 (8.10%)	
number of deaths (all causes)	2	0	
number of deaths resulting from adverse events			
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional self-injury			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			

subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amnesia			

subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 248 (0.40%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis chronic			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			

subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 248 (0.40%)	2 / 247 (0.81%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			

subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingitis			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	1 / 248 (0.40%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	DTG 50 mg/ABC 600 mg/3TC 300 mg QD	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	132 / 248 (53.23%)	160 / 247 (64.78%)	
Nervous system disorders			
Headache			
subjects affected / exposed	29 / 248 (11.69%)	32 / 247 (12.96%)	
occurrences (all)	50	38	
Dizziness			
subjects affected / exposed	13 / 248 (5.24%)	15 / 247 (6.07%)	
occurrences (all)	16	15	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 248 (3.23%)	14 / 247 (5.67%)	
occurrences (all)	10	15	
Eye disorders			
Ocular icterus			
subjects affected / exposed	0 / 248 (0.00%)	18 / 247 (7.29%)	
occurrences (all)	0	21	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	47 / 248 (18.95%)	48 / 247 (19.43%)	
occurrences (all)	55	62	
Diarrhoea			
subjects affected / exposed	24 / 248 (9.68%)	32 / 247 (12.96%)	
occurrences (all)	25	37	
Dyspepsia			
subjects affected / exposed	9 / 248 (3.63%)	25 / 247 (10.12%)	
occurrences (all)	17	29	
Vomiting			
subjects affected / exposed	17 / 248 (6.85%)	17 / 247 (6.88%)	
occurrences (all)	18	41	
Abdominal pain			
subjects affected / exposed	8 / 248 (3.23%)	17 / 247 (6.88%)	
occurrences (all)	8	20	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	10 / 248 (4.03%)	26 / 247 (10.53%)	
occurrences (all)	11	27	
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 248 (0.00%)	14 / 247 (5.67%)	
occurrences (all)	0	14	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 248 (0.00%)	13 / 247 (5.26%)	
occurrences (all)	0	16	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	12 / 248 (4.84%)	20 / 247 (8.10%)	
occurrences (all)	13	22	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	13 / 248 (5.24%)	17 / 247 (6.88%)	
occurrences (all)	13	18	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	19 / 248 (7.66%)	20 / 247 (8.10%)	
occurrences (all)	23	23	
Nasopharyngitis			
subjects affected / exposed	16 / 248 (6.45%)	14 / 247 (5.67%)	
occurrences (all)	19	16	
Urinary tract infection			
subjects affected / exposed	13 / 248 (5.24%)	16 / 247 (6.48%)	
occurrences (all)	14	16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported