Clinical trial results:
A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir DF or Efavirenz /Emtricitabine/Tenofovir DF) compared to Ritonavir boosted Atazanavir plus Abacavir/Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR 70 mL/min

Summary

EudraCT number	2014-002095-93
Trial protocol	GB BE ES IE
Global end of trial date	17 February 2016

Results information

Result version number	v3 (current)
This version publication date	21 August 2017
First version publication date	06 March 2017
Version creation reason	• Correction of full data set Updated description for 3 endpoints for clarification regarding the data.

Trial information

Trial identification

Sponsor protocol code	GS-US-236-0140

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02246998
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, United States, 94404
Public contact	Clinical Trials Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com
Scientific contact	Clinical Trials Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 February 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to assess glomerular function before and during administration of stribild (STB; elvitegravir/ cobicistat/emtricitabine/tenofovir disoproxil fumarate (E/C/F/TDF)) or a regimen containing TDF without cobicistat (COBI) as ritonavir (RTV)-boosted atazanavir (ATV/r) plus truvada (TVD; FTC/TDF) or atripla (ATR; efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF)) compared to a regimen containing neither TDF nor COBI as ATV/r plus abacavir/lamivudine (ABC/3TC) via determination of actual glomerular filtration rate (aGFR) using iohexol (a probe GFR marker) plasma clearance and estimated (calculated) glomerular filtration rate (eGFR).

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	United Kingdom: 37
Country: Number of subjects enrolled	Belgium: 14
Country: Number of subjects enrolled	Ireland: 5
Worldwide total number of subjects	72
EEA total number of subjects	72

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)	72
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Belgium, Ireland, Spain, and the United Kingdom. The first participant was screened on 15 Dec 2014. The last study visit occurred on 17 February 2016.

Pre-assignment

Screening details:

93 participants were screened.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Stribild (STB)

Arm description:

Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (STB; Stribild®; EVG/COBI/FTC/TDF; 150/150/200/300 mg) FDC tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24

Arm type	Experimental
Investigational medicinal product name	Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate
Investigational medicinal product code	
Other name	Stribild®; EVG/COBI/FTC/TDF
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150/150/200/300 mg FDC orally with food once daily for 24 weeks

Investigational medicinal product name	Iohexol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg solution at Baseline (Day1), and Weeks 4, 8, 16, and 24

Arm title	TVD + ATV/r

Arm description:

FTC/TDF (TVD; Truvada®; 200/300 mg) FDC tablet + Atazanavir (ATV) 300 mg capsule + Ritonavir (RTV) 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day 1), and Weeks 4, 8, 16, and 24

Arm type	Experimental
Investigational medicinal product name	FTC/TDF
Investigational medicinal product code	
Other name	TVD; Truvada®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200/300 mg FDC with food once daily for 24 weeks

Investigational medicinal product name	Atazanavir
Investigational medicinal product code	
Other name	ATV
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

300 mg orally with food once daily for 24 weeks

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

Dosage and administration details:

100 mg orally with food once daily for 24 weeks

Investigational medicinal product name	Iohexol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg solution at Baseline (Day1), and Weeks 4, 8, 16, and 24

Arm title	Atripla (ATR)

Arm description:

EFV/FTC/TDF (ATR; Atripla® 600/200/300 mg) FDC tablet orally once daily on an empty stomach for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24

Arm type	Experimental
Investigational medicinal product name	EFV/FTC/TDF
Investigational medicinal product code	
Other name	ATR; Atripla®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

600/200/300 mg FDC once daily on an empty stomach for 24 weeks

Investigational medicinal product name	Iohexol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg solution at Baseline (Day1), and Weeks 4, 8, 16, and 24

Arm title	ABC/3TC + ATV/r

Arm description:

ABC/3TC (600/300 mg) FDC tablet + ATV 300 mg capsule + RTV 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24

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

Dosage and administration details: 600/300 mg FDC with food once daily for 24 weeks	
Investigational medicinal product name	RTV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 100 mg with food once daily for 24 weeks	
Investigational medicinal product name	Iohexol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use
Dosage and administration details: 1500 mg solution at Baseline (Day1), and Weeks 4, 8, 16, and 24	

Number of subjects in period 1[1]	Stribild (STB)	TVD + ATV/r	Atripla (ATR)
Started	17	16	16
Completed	16	15	15
Not completed	1	1	1
Adverse event, non-fatal	-	1	1
Lost to follow-up	1	-	-

Number of subjects in period 1[1]	ABC/3TC + ATV/r
Started	17
Completed	16
Not completed	1
Adverse event, non-fatal	-
Lost to follow-up	1

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: 6 participants who were randomized but not treated is are not included in the subject disposition table.

Baseline characteristics

Reporting groups	
Reporting group title	Stribild (STB)
Reporting group description:	
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (STB; Stribild®; EVG/COBI/FTC/TDF; 150/150/200/300 mg) FDC tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	
Reporting group title	TVD + ATV/r
Reporting group description:	
FTC/TDF (TVD; Truvada®; 200/300 mg) FDC tablet + Atazanavir (ATV) 300 mg capsule + Ritonavir (RTV) 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day 1), and Weeks 4, 8, 16, and 24	
Reporting group title	Atripla (ATR)
Reporting group description:	
EFV/FTC/TDF (ATR; Atripla® 600/200/300 mg) FDC tablet orally once daily on an empty stomach for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	
Reporting group title	ABC/3TC + ATV/r
Reporting group description:	
ABC/3TC (600/300 mg) FDC tablet + ATV 300 mg capsule + RTV 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	

Reporting group values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)
Number of subjects	17	16	16
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	36	34	34
standard deviation	± 8.1	± 8.4	± 9.6
Gender categorical Units: Subjects			
Female	0	1	1
Male	17	15	15
Race Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	1	0	0
Black	2	1	2
White	13	15	13
Other	0	0	1
Ethinicity Units: Subjects			
Hispanic or Latino	2	3	2
Not Hispanic or Latino	15	13	14
Actual Glomerular Filtration Rate Units: mL/min			
arithmetic mean	111.8	112	105.4

standard deviation	± 31.07	± 19.17	± 38.22
Estimated Glomerular Filtration Rate by Cockcroft- Gault			
Units: mL/min			
arithmetic mean	120.8	121.2	119.5
standard deviation	± 13.94	± 24.34	± 20.36
Estimated Glomerular Filtration Rate by MDRD Formula			
Units: mL/ min/1.73m^2			
arithmetic mean	103.8	110.6	108.4
standard deviation	± 14.06	± 18.47	± 21.42
CD4 Cell Count			
Units: cells/µL			
arithmetic mean	552	600	553
standard deviation	± 177.8	± 217.9	± 215.8

Reporting group values	ABC/3TC + ATV/r	Total	
Number of subjects	17	66	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	34		
standard deviation	± 7.5	-	
Gender categorical			
Units: Subjects			
Female	0	2	
Male	17	64	
Race			
Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	1	2	
Black	1	6	
White	15	56	
Other	0	1	
Ethinicity			
Units: Subjects			
Hispanic or Latino	0	7	
Not Hispanic or Latino	17	59	
Actual Glomerular Filtration Rate			
Units: mL/min			
arithmetic mean	96.6		
standard deviation	± 34.52	-	
Estimated Glomerular Filtration Rate by Cockcroft- Gault			
Units: mL/min			
arithmetic mean	122.6		
standard deviation	± 20.25	-	
Estimated Glomerular Filtration Rate by MDRD Formula			
Units: mL/ min/1.73m^2			
arithmetic mean	105.5		

standard deviation	± 12.59	-	
CD4 Cell Count			
Units: cells/µL			
arithmetic mean	524		
standard deviation	± 190	-	

End points

End points reporting groups

Reporting group title	Stribild (STB)
Reporting group description:	
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (STB; Stribild®; EVG/COBI/FTC/TDF; 150/150/200/300 mg) FDC tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	
Reporting group title	TVD + ATV/r
Reporting group description:	
FTC/TDF (TVD; Truvada®; 200/300 mg) FDC tablet + Atazanavir (ATV) 300 mg capsule + Ritonavir (RTV) 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day 1), and Weeks 4, 8, 16, and 24	
Reporting group title	Atripla (ATR)
Reporting group description:	
EFV/FTC/TDF (ATR; Atripla® 600/200/300 mg) FDC tablet orally once daily on an empty stomach for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	
Reporting group title	ABC/3TC + ATV/r
Reporting group description:	
ABC/3TC (600/300 mg) FDC tablet + ATV 300 mg capsule + RTV 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	

Primary: Actual Glomerular Filtration Rate (aGFR) Using Iohexol Plasma Clearance (CLiohexol) at Week 24

End point title	Actual Glomerular Filtration Rate (aGFR) Using Iohexol Plasma Clearance (CLiohexol) at Week 24[1]
End point description:	
Participants in the pharmacodynamics (PD) analysis Set (all treated participants in each group, who have evaluable baseline and at least 1 postbaseline aGFR and /or eGFR at any visit) with available data were analyzed.	
End point type	Primary
End point timeframe:	
Week 24	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No statistical comparison was planned or performed.	

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	15	15	17
Units: mL/min				
arithmetic mean (standard deviation)	103.6 (± 23.28)	104.9 (± 27.16)	111.1 (± 23.23)	101 (± 27.01)

Statistical analyses

No statistical analyses for this end point

Primary: Estimated GFR (eGFR) Calculated by Cockcroft-Gault Formula at Week 24

End point title	Estimated GFR (eGFR) Calculated by Cockcroft-Gault Formula at Week 24[2]

End point description:

GFR is a measure of the rate at which blood is filtered by the kidney. Cockcroft-Gault is an equation (calculation) used to estimate GFR based on serum creatinine, weight, and gender. eGFR = (140 - age) * (mass in kg) * (0.85 if female) divided by 72 * serum creatinine in mg/dL. Participants in the PD Analysis Set with available data were analyzed.

End point type	Primary

End point timeframe:

Week 24

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	16
Units: mL/min				
arithmetic mean (standard deviation)	116.9 (± 17.06)	122.4 (± 31.71)	120 (± 20.52)	123 (± 25.74)

Statistical analyses

No statistical analyses for this end point

Primary: Estimated GFR Calculated by Modification of Diet in Renal Disease (MDRD) Formula at Week 24

End point title	Estimated GFR Calculated by Modification of Diet in Renal Disease (MDRD) Formula at Week 24[3]

End point description:

MDRD is an equation (calculation) used to estimate GFR in participants with impaired renal function based on serum creatinine, age, race, and gender. eGFR (mL/min/1.73 m^2) = 186 * (Scr)^-1.154 * (Age)^(-0.203) * (0.742 if female) * (1.212 if black). Scr = serum creatinine in mg/dL. Participants in the PD Analysis Set with available data were analyzed.

End point type	Primary

End point timeframe:

Week 24

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	16
Units: mL/min/1.73m^2				
arithmetic mean (standard deviation)	99.3 (± 17.07)	110.2 (± 23.98)	109.2 (± 20.9)	104.9 (± 12.59)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Treatment-Emergent Graded Laboratory Abnormality: Urine Glucose (by Dipstick)

End point title	Percentage of Participants Experiencing Treatment-Emergent Graded Laboratory Abnormality: Urine Glucose (by Dipstick)
End point description:	
Safety Analysis Set	
End point type	Secondary
End point timeframe:	
Up to 24 weeks plus 30 days	

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	16	17
Units: Participants				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Any Grade	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Treatment-Emergent Graded Laboratory Abnormality: Serum Glucose (Fasting)

End point title	Percentage of Participants Experiencing Treatment-Emergent Graded Laboratory Abnormality: Serum Glucose (Fasting)
End point description:	
Participants in the Safety Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Up to 24 weeks plus 30 days	

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	15	17
Units: percentage of participants				
number (not applicable)				
Grade 1 (Hyperglycemia)	11.8	12.5	20	0
Grade 1 (Hypoglycemia)	0	0	0	0
Grade 2 (Hyperglycemia)	0	0	0	0
Grade 2 (Hypoglycemia)	0	6.3	0	0
Grade 3 (Hyperglycemia)	0	0	0	0
Grade 3 (Hypoglycemia)	0	0	0	0
Grade 4 (Hyperglycemia)	0	0	0	0
Grade 4 (Hypoglycemia)	0	0	0	0
Any grade (Hyperglycemia)	11.8	12.5	20	0
Any grade (Hypoglycemia)	0	6.3	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Urine Albumin to Creatinine Ratio (mg/g) at Week 24

End point title	Percentage Change From Baseline in Urine Albumin to Creatinine Ratio (mg/g) at Week 24
End point description:	
Participants in the PD Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 24	

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	14	13	17
Units: percentage change				
median (inter-quartile range (Q1-Q3))	0 (-23.6 to 50)	-18.3 (-57.1 to 50)	50 (-25 to 100)	-16.7 (-37.5 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Urine Protein to Creatinine Ratio (mg/g) at Week 24

End point title	Percentage Change From Baseline in Urine Protein to Creatinine Ratio (mg/g) at Week 24

End point description:

Participants in the PD Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 24

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	14	15	17
Units: percentage change				
median (inter-quartile range (Q1-Q3))	5.7 (-11 to 22.5)	17.5 (0 to 45.7)	-10.5 (-41.9 to 69.8)	7.1 (-24.3 to 13.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Urine β2-microglobulin to Creatinine Ratio (µg/g) at Week 24

End point title	Percentage Change From Baseline in Urine β2-microglobulin to Creatinine Ratio (µg/g) at Week 24

End point description:

Participants in the PD Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline ; Week 24

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	14	13	17
Units: percentage change				
median (inter-quartile range (Q1-Q3))	-5.1 (-48.2 to 22.8)	197.3 (21.7 to 328.7)	-1.1 (-33.1 to 36.7)	-22.7 (-60.8 to -6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Urine Retinol Binding Protein (RBP) to Creatinine Ratio (µg/g) at Week 24

End point title	Percentage Change From Baseline in Urine Retinol Binding Protein (RBP) to Creatinine Ratio (µg/g) at Week 24

End point description:

Participants in the PD Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 24

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	14	13	17
Units: percentage change				
median (inter-quartile range (Q1-Q3))	38.1 (-1.1 to 51.1)	52.2 (5.9 to 147.6)	52.1 (-33.8 to 92.8)	4.8 (-13.6 to 15.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic (PK) Parameter: Cmax for COBI

End point title	Pharmacokinetic (PK) Parameter: Cmax for COBI[4]

End point description:

Cmax is defined as the maximum observed concentration of drug in plasma. Participants in the COBI PK Analysis Set (all treated participants who have respective, evaluable PK profiles of COBI) with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla) and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	1189.1 (± 377.88)			
Week 8	1017.8 (± 388.09)			

Week 16	1197.3 (± 656.33)			
Week 24 (N= 16)	1123.4 (± 430.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Tmax for COBI

End point title	PK Parameter: Tmax for COBI[5]

End point description:

Tmax is defined as the time of Cmax. Participants in the COBI PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4	3.3 (3 to 4.1)			
Week 8	3.1 (3 to 4.1)			
Week 16	3.1 (2.1 to 4)			
Week 24 (N= 16)	3 (2.1 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Clast for COBI

End point title	PK Parameter: Clast for COBI[6]

End point description:

Clast is defined as the last observable concentration of drug. Participants in the COBI PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	85 (± 126.69)			
Week 8	54.5 (± 59.58)			
Week 16	214 (± 693.66)			
Week 24 (N=16)	162.7 (± 299.48)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Tlast for COBI

End point title	PK Parameter: Tlast for COBI[7]

End point description:

Tlast is defined as the time of Clast. Participants in the COBI PK Analysis Set with available data were analyzed. Plasma samples for PK analysis were collected out to 10 hours postdose, and the predose concentration was used as a surrogate for the 24 hour concentration for PK parameter generation.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4	24 (24 to 24)			
Week 8	24 (24 to 24)			
Week 16	24 (24 to 24)			
Week 24 (N=16)	24 (10.1 to 24)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Ctau for COBI

End point title	PK Parameter: Ctau for COBI[8]

End point description:

Ctau is defined as the observed drug concentration at the end of the dosing interval. Participants in the

COBI PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	59.7 (± 113.31)			
Week 8	26 (± 28.79)			
Week 16	198.3 (± 697.06)			
Week 24	82.7 (± 285.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: λz for COBI

End point title	PK Parameter: λz for COBI[9]

End point description:

λz is defined as the terminal elimination rate constant. Participants in the COBI PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: 1/hour				
arithmetic mean (standard deviation)				
Week 4	0.179 (± 0.0598)			
Week 8 (N= 15)	0.192 (± 0.0481)			
Week 16 (N= 16)	0.206 (± 0.061)			
Week 24 (N=15)	0.211 (± 0.0844)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: AUCtau for COBI

End point title	PK Parameter: AUCtau for COBI[10]

End point description:

AUCtau is defined as the concentration of drug over time (area under the plasma concentration versus time curve over
the dosing interval). Participants in the COBI PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: h*ng/mL				
arithmetic mean (standard deviation)				
Week 4 (N=16)	9225.8 (± 2786.6)			
Week 8 (N=15)	8127.4 (± 3217.12)			
Week 16 (N=17)	10684.8 (± 12567.09)			
Week 24 (N=15)	8391.3 (± 6132.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: t1/2 for COBI

End point title	PK Parameter: t1/2 for COBI[11]

End point description:

t1/2 is defined as the estimate of the terminal elimination half-life of the drug. Participants in the COBI PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: COBI was not administered in arms: TVD + ATV/ r, ATR (Atripla), and ABC/3TC + ATV/r

End point values	Stribild (STB)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4 (N= 16)	3.8 (3.24 to 4.63)			
Week 8 (N= 15)	4.09 (2.89 to 4.75)			
Week 16 (N= 16)	3.42 (2.91 to 4.18)			
Week 24 (N= 15)	3.24 (2.57 to 4.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Cmax for RTV

End point title	PK Parameter: Cmax for RTV[12]

End point description:

Participants in the RTV PK Analysis Set (all treated participants who have respective, evaluable PK profiles of RTV) with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	1260 (± 453.58)	1352.1 (± 513.74)		
Week 8	1142.3 (± 489.18)	1326.2 (± 493.47)		
Week 16 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=17)	1144.8 (± 416.41)	1557.6 (± 555.87)		
Week 24 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=17)	1217.7 (± 445.18)	1485.4 (± 662.49)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Tmax for RTV

End point title	PK Parameter: Tmax for RTV[13]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4	4 (3.2 to 4.6)	4 (2.1 to 4.1)		
Week 8	4 (2.5 to 5.1)	4 (3 to 4.1)		
Week 16 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=17)	4.1 (3 to 5.1)	4 (2.2 to 4.1)		
Week 24 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=17)	4 (3 to 5)	4 (3 to 4.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Clast for RTV

End point title	PK Parameter: Clast for RTV[14]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	59.5 (± 57.85)	61 (± 56.51)		
Week 8	71 (± 91.24)	85.5 (± 99.68)		
Week 16 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=17)	69.2 (± 49.85)	99.1 (± 92.42)		
Week 24 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=17)	102.5 (± 182.16)	187.9 (± 258.53)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Tlast for RTV

End point title	PK Parameter: Tlast for RTV[15]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed. Plasma samples for PK analysis were collected out to 10 hours postdose, and the predose concentration was used as a surrogate for the 24 hour concentration for PK parameter generation.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4	24 (24 to 24)	24 (24 to 24)		
Week 8	24 (24 to 24)	24 (24 to 24)		
Week 16 (TVD+ATV/r: N= 15)	24 (24 to 24)	24 (24 to 24)		
Week 24 (TVD+ATV/r: N= 15)	24 (24 to 24)	24 (24 to 24)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Ctau for RTV

End point title	PK Parameter: Ctau for RTV[16]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	59.5 (± 57.85)	61 (± 56.51)		
Week 8	71 (± 91.24)	85.5 (± 99.68)		
Week 16 (TVD+ATV/r: N= 15)	69.2 (± 49.85)	99.1 (± 92.42)		
Week 24 (TVD+ATV/r: N= 15)	102.5 (± 182.16)	157 (± 246.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: AUCtau for RTV

End point title	PK Parameter: AUCtau for RTV[17]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: h*ng/mL				
arithmetic mean (standard deviation)				
Week 4	8259.6 (± 3166.47)	9649.1 (± 3713.87)		
Week 8	8362 (± 3544.53)	9702.2 (± 3391.68)		
Week 16 (TVD+ATV/r: N= 15)	8102.6 (± 3392)	11148 (± 4482.33)		
Week 16 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=16)	8907 (± 5182.65)	12039.3 (± 6792.06)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: λz for RTV

End point title	PK Parameter: λz for RTV[18]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: 1/hour				
arithmetic mean (standard deviation)				
Week 4 (TVD+ATV/r: N= 14; ABC/3TC + ATV/r: N=15)	0.156 (± 0.0386)	0.151 (± 0.0346)		
Week 8 (TVD+ATV/r: N= 13; ABC/3TC + ATV/r: N=15)	0.144 (± 0.0474)	0.142 (± 0.0281)		
Week 16 (TVD+ATV/r: N= 12; ABC/3TC + ATV/r: N=17)	0.138 (± 0.0382)	0.131 (± 0.0291)		
Week 24 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=15)	0.133 (± 0.0347)	0.128 (± 0.0469)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: t1/2 for RTV

End point title	PK Parameter: t1/2 for RTV[19]

End point description:

Participants in the RTV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ATV boosted with RTV (ATV/r) was not administered in arms: Stribild (STB) and Atripla (ATR)

End point values	TVD + ATV/r	ABC/3TC + ATV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: hours				
arithmetic mean (full range (min-max))				
Week 4 (TVD+ATV/r: N= 14; ABC/3TC + ATV/r: N=15)	4.56 (3.77 to 4.99)	4.53 (3.83 to 6.01)		
Week 8 (TVD+ATV/r: N= 13; ABC/3TC + ATV/r: N=15)	4.85 (3.75 to 5.34)	4.68 (4.31 to 5.69)		
Week 16 (TVD+ATV/r: N= 12; ABC/3TC + ATV/r: N=17)	5.39 (4.22 to 6.22)	5.57 (4.68 to 6)		
Week 24 (TVD+ATV/r: N= 15; ABC/3TC + ATV/r: N=15)	5.08 (4.49 to 5.78)	4.82 (4.25 to 6.41)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Cmax for TFV

End point title	PK Parameter: Cmax for TFV[20]

End point description:

Participants in the TFV PK Analysis Set (all treated participants who have respective, evaluable PK profiles of TFV) with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	371.2 (± 94.46)	301.6 (± 116.36)	298.3 (± 100.36)	
Week 8 (ATR: N= 14)	379.8 (± 87.44)	343 (± 133.97)	325.5 (± 149.48)	
Week 16 (TVD + ATV/r: N= 15; ATR: N= 15)	399.5 (± 169.51)	319.4 (± 146.41)	298.6 (± 107.11)	
Week 24(STB: N= 16; TVD + ATV/r: N= 15; ATR: N=15)	394.4 (± 131.09)	350.7 (± 126.91)	305.9 (± 106.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Tmax for TFV

End point title	PK Parameter: Tmax for TFV[21]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4	2 (1.3 to 3.1)	3 (1.5 to 3.1)	1.1 (0.6 to 2)	
Week 8 (ATR: N=14)	2 (2 to 2.1)	3 (2 to 3.1)	1 (0.6 to 1.1)	
Week 16 (TVD + ATV/r: N= 15)	2.1 (1.1 to 3.1)	2.1 (1 to 3.1)	1.2 (1 to 2.1)	
Week 24 (STB: N= 16; TVD + ATV/r: N= 15)	2 (1.1 to 3)	2.1 (1.1 to 3.2)	1.1 (0.6 to 2)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Clast for TFV

End point title	PK Parameter: Clast for TFV[22]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	81.1 (± 32.41)	73.1 (± 23.74)	55.4 (± 15.52)	
Week 8 (ATR: N=14)	80.9 (± 35.12)	78.2 (± 31.27)	53.4 (± 18.83)	
Week 16 (TVD + ATV/r: N= 15; ATR: N= 15)	128.5 (± 184.17)	74.5 (± 26.01)	63 (± 19.25)	
Week 24 (STB: N= 16; TVD+ATV/r: N= 15; ATR: N=15)	78.5 (± 53.04)	87.3 (± 41.2)	58.5 (± 16.45)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Tlast for TFV

End point title	PK Parameter: Tlast for TFV[23]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed. Plasma samples for PK analysis were collected out to 10 hours postdose, and the predose concentration was used as a surrogate for the 24 hour concentration for PK parameter generation.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4	24 (24 to 24)	24 (24 to 24)	24 (24 to 24)	
Week 8 (ATR: N= 14)	24 (24 to 24)	24 (24 to 24)	24 (24 to 24)	
Week 16 (TVD + ATV/r: N= 15; ATR: N= 15)	24 (24 to 24)	24 (24 to 24)	24 (24 to 24)	

Week 24 (STB: N= 16; TVD+ATV/r: N= 15; ATR: N=15)	24 (24 to 24)	24 (24 to 24)	24 (24 to 24)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Ctau for TFV

End point title	PK Parameter: Ctau for TFV[24]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4	74.6 (± 36.88)	73.1 (± 23.74)	55.4 (± 15.52)	
Week 8 (ATR: N= 14)	75.8 (± 40.16)	78.2 (± 31.27)	48.8 (± 23.27)	
Week 16 (TVD + ATV/r: N= 15; ATR: N= 15)	128.5 (± 184.17)	74.5 (± 26.01)	57.5 (± 24.41)	
Week 24 (TVD + ATV/r: N= 15; ATR: N= 15)	71.7 (± 57.06)	77.3 (± 43.06)	54.2 (± 22.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: λz for TFV

End point title	PK Parameter: λz for TFV[25]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Weeks 4, 8, 16, and 24

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: 1/hour				
arithmetic mean (standard deviation)				
Week 4 (TVD + ATV/r: N= 15)	0.045 (± 0.0148)	0.048 (± 0.0059)	0.037 (± 0.0133)	
Week 8 (TVD + ATV/r: N= 15; ATR: N= 13)	0.051 (± 0.0167)	0.048 (± 0.0158)	0.041 (± 0.0197)	
Week 16 (STB: N= 16; TVD+ATV/r: N= 14; ATR: N=15)	0.047 (± 0.0173)	0.047 (± 0.0115)	0.033 (± 0.0166)	
Week 24 (STB: N= 16; TVD+ATV/r: N= 15; ATR: N=15)	0.051 (± 0.0195)	0.046 (± 0.0184)	0.035 (± 0.0138)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: AUCtau for TFV

End point title	PK Parameter: AUCtau for TFV[26]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: h*ng/mL				
arithmetic mean (standard deviation)				
Week 4	3370.2 (± 1000.75)	3151.2 (± 1107.18)	2244.8 (± 572.09)	
Week 8 (ATR: N= 14)	3549.7 (± 1238.03)	3361.9 (± 1152.04)	2250.8 (± 555.79)	
Week 16 (TVD + ATV/r: N= 15; ATR: N= 15)	3939.7 (± 2499.63)	3234.7 (± 1207.58)	2326.4 (± 494.24)	
Week 24 (STB: N= 16; TVD+ATV/r: N= 15; ATR: N=15)	3307 (± 1387.97)	3451.5 (± 1075.47)	2265.7 (± 412.87)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: t1/2 for TFV

End point title	PK Parameter: t1/2 for TFV[27]

End point description:

Participants in the TFV PK Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" at Weeks 4, 8, 16, and 24

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: TDF (which is metabolized to TFV) was not administered in arm: ABC/3TC + ATV/r

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	15	
Units: hours				
median (inter-quartile range (Q1-Q3))				
Week 4 (TVD + ATV/r: N= 15)	15.73 (12.49 to 18.9)	14.1 (13.28 to 16.81)	20.65 (15.3 to 26.75)	
Week 8 (TVD + ATV/r: N= 16; ATR: N= 13)	14.4 (12.07 to 16.83)	15.82 (11.94 to 19.53)	18.81 (13.08 to 25.14)	
Week 16 (STB: N= 16; TVD+ATV/r: N= 14; ATR: N=15)	14.41 (13.11 to 19.87)	14.72 (12.76 to 16.73)	22.78 (16.88 to 32.15)	
Week 24 (STB: N= 16; TVD+ATV/r: N= 15; ATR: N=15)	13.99 (11.91 to 18.52)	16.17 (13.18 to 21.37)	21.54 (19.39 to 27.32)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: AUCinf for Iohexol

End point title	PK Parameter: AUCinf for Iohexol

End point description:

AUC inf is defined as the concentration of drug extrapolated to infinite time (area under the plasma concentration
versus time curve extrapolated to infinite time). Participants in the iohexol PK Analysis Set (all treated participants who have respective, evaluable PK profiles of iohexol) with available data were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 0.5, 1, 2, 3, 4, 5, 6, and 10 hours post "time zero" on Day 1 and Weeks 4, 8, 16, and 24

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	16	17
Units: h*µg/mL				
arithmetic mean (standard deviation)				
Day 1	511.2 (± 172.71)	486.8 (± 108.28)	706.9 (± 647.25)	695.2 (± 523.33)
Week 4 (ATR: N= 14)	521.8 (± 121.67)	496.2 (± 153.05)	512.6 (± 163.89)	720.5 (± 657.95)
Week 8 (ATR: N= 15; ABC/3TC + ATV/r: N= 16))	517.8 (± 170.24)	574.8 (± 382.63)	510.6 (± 136.4)	667 (± 559.06)
Week 16 (TVD + ATV/r: N= 15; ATR: N= 15)	494.3 (± 113.6)	509.5 (± 156.98)	504.8 (± 95.07)	725.9 (± 843.22)
Week 24 (TVD + ATV/r: N= 15; ATR: N= 15)	545.8 (± 127.34)	561.2 (± 214.26)	507.1 (± 113.45)	606.5 (± 321.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HIV-1 RNA < 50 Copies/mL Week 24 as Determined by Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA < 50 Copies/mL Week 24 as Determined by Snapshot Algorithm

End point description:

Full Analysis Set (FAS): all participants who (1) are randomized into the study and (2) have received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Week 24

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	13	15
Units: percentage of participants				
number (not applicable)	88.2	81.3	81.3	88.2

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Cluster of Differentiation 4 Positive (CD4+) Cell Count at Week 24

End point title	Change From Baseline in Cluster of Differentiation 4 Positive (CD4+) Cell Count at Week 24

End point description: Full Analysis Set	
End point type	Secondary
End point timeframe: Baseline; Week 24	

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	17
Units: cell/µL				
arithmetic mean (standard deviation)	139.63 (± 142.196)	217.6 (± 195.375)	204.33 (± 194.653)	237.29 (± 201.222)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Adverse Events (AEs)	
End point title	Percentage of Participants Experiencing Adverse Events (AEs)
End point description: Safety Analysis Set	
End point type	Secondary
End point timeframe: Up to the last dose date plus 30 days (Up to 24 weeks plus 30 days)	

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	16	17
Units: percentage of participants				
number (not applicable)				
Any Treatment-Emergent Adverse Events (TEAE)	70.6	87.5	87.5	88.2
Any Grade 3 or 4 Treatment-Emergent Adverse Event	5.9	12.5	12.5	5.9
Any Treatment-Emergent Study-Drug-Related AEs	11.8	50	68.8	23.5
Any TEAE Leading to Study Drug Discontinuation	5.9	6.3	6.3	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Treatment Emergent (TE) Grade 3 or 4 Laboratory Abnormalities

End point title	Percentage of Participants Experiencing Treatment Emergent (TE) Grade 3 or 4 Laboratory Abnormalities

End point description:

Graded laboratory abnormalities were defined as values that increased at least one toxicity grade from predose at any postdose up to the last dose date of study drug plus 30 days. The most severe graded abnormality from all tests was counted for each participant. Safety Analysis Set

End point type	Secondary

End point timeframe:

Up to the last dose date plus 30 days (Up to 24 weeks plus 30 days)

End point values	Stribild (STB)	TVD + ATV/r	Atripla (ATR)	ABC/3TC + ATV/r
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	16	17
Units: Percentage of participants				
number (not applicable)				
Any Grade 3 or 4 TE Laboratory Abnormality	5.9	25	12.5	52.9
Grade 3 or 4 Neutrophils	0	6.3	0	0
Grade 3 or 4 Amylase	0	0	6.3	0
Grade 3 or 4 AST	0	6.3	0	0
Grade 3 or 4 CK	5.9	18.8	6.3	5.9
Grade 3 or 4 Total Bilirubin	0	12.5	0	52.9
Grade 3 or 4 Urine RBC	0	7.7	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Baseline to 30 days after last dose of study drug (up to 24 weeks plus 30 days)	
Adverse event reporting additional description:	
Safety Analysis Set	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	Stribild (STB)
Reporting group description:	
STB (150/150/200/300 mg) FDC tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	
Reporting group title	TVD + ATV/r
Reporting group description:	
TVD (200/300 mg) FDC tablet + ATV 300 mg capsule + RTV 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day 1), and Weeks 4, 8, 16, and 24	
Reporting group title	Atripla (ATR)
Reporting group description:	
ATR (600/200/300 mg) FDC tablet orally once daily on an empty stomach for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	
Reporting group title	ABC/3TC + ATV/r
Reporting group description:	
ABC/3TC (600/300 mg) FDC tablet + ATV 300 mg capsule + RTV 100 mg tablet orally with food once daily for 24 weeks + iohexol 1500 mg solution administered intravenously at Baseline (Day1), and Weeks 4, 8, 16, and 24	

Serious adverse events	Stribild (STB)	TVD + ATV/r	Atripla (ATR)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	1 / 16 (6.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Liver injury			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Intentional self-injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABC/3TC + ATV/r		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 17 (11.76%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Overdose			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Liver injury			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Intentional self-injury			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Stribild (STB)	TVD + ATV/r	Atripla (ATR)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 17 (64.71%)	14 / 16 (87.50%)	13 / 16 (81.25%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Spider vein			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 17 (11.76%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Abnormal dreams			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Disorientation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Indifference			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1

Nightmare			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Sleep disorder			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Terminal insomnia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Liver function test abnormal			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2
Traumatic haematoma			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	7 / 16 (43.75%)
occurrences (all)	0	1	7
Head discomfort			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	2 / 17 (11.76%)	1 / 16 (6.25%)	2 / 16 (12.50%)
occurrences (all)	2	2	2
Hypoaesthesia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Lethargy			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Nervous system disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ocular icterus			
subjects affected / exposed	0 / 17 (0.00%)	3 / 16 (18.75%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Anal fissure			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 17 (5.88%)	2 / 16 (12.50%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	4
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	4
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	2 / 16 (12.50%)
occurrences (all)	0	2	2
Rash erythematous			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute hepatitis C			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Anal chlamydia infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eye abscess			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Eyelid boil			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Furuncle			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gonorrhoea			

subjects affected / exposed	0 / 17 (0.00%)	3 / 16 (18.75%)	1 / 16 (6.25%)
occurrences (all)	0	3	1
Laryngitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 17 (5.88%)	3 / 16 (18.75%)	3 / 16 (18.75%)
occurrences (all)	1	3	3
Onychoclasis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Syphilis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Tinea cruris			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Tinea versicolour			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Increased appetite			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	ABC/3TC + ATV/r		
Total subjects affected by non-serious adverse events			

subjects affected / exposed	14 / 17 (82.35%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Spider vein			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Abnormal dreams			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Depressed mood			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Indifference			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Nightmare			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Terminal insomnia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Liver function test abnormal			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Traumatic haematoma			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Head discomfort			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	3 / 17 (17.65%)		
occurrences (all)	5		
Hypoaesthesia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lethargy			

subjects affected / exposed occurrences (all) Nervous system disorder subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0 0 / 17 (0.00%) 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	 1 / 17 (5.88%) 1		
Eye disorders Eye pain subjects affected / exposed occurrences (all) Ocular icterus subjects affected / exposed occurrences (all)	 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0		
Gastrointestinal disorders Anal fissure subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Diarrhoea haemorrhagic subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all) Dyspepsia subjects affected / exposed occurrences (all) Flatulence subjects affected / exposed occurrences (all) Haemorrhoids	 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 1 / 17 (5.88%) 1		

subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Toothache subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 1 / 17 (5.88%) 1 1 / 17 (5.88%) 1		
Hepatobiliary disorders Jaundice subjects affected / exposed occurrences (all)	 1 / 17 (5.88%) 1		
Skin and subcutaneous tissue disorders Dermatitis allergic subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Ingrowing nail subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Rash erythematous subjects affected / exposed occurrences (all)	 1 / 17 (5.88%) 1 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Infections and infestations			
Acute hepatitis C			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Anal chlamydia infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eye abscess			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eyelid boil			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Fungal skin infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Furuncle			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Gonorrhoea			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Laryngitis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Onychoclasis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Otitis externa			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Syphilis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tinea cruris			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tinea versicolour			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Increased appetite			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

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