



Clinical trial results:

A Study to Compare the Pharmacokinetics of a Fixed-Dose Combination of Raltegravir and Lamivudine to Co-administered Raltegravir and Lamivudine

Summary

EudraCT number	2015-002237-22
Trial protocol	Outside EU/EEA
Global end of trial date	25 September 2011

Results information

Result version number	v1 (current)
This version publication date	01 March 2016
First version publication date	15 July 2015

Trial information

Trial identification

Sponsor protocol code	MK-0518B-196
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001442-PIP01-13
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	25 September 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 September 2011
Global end of trial reached?	Yes
Global end of trial date	25 September 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assess the plasma pharmacokinetic profiles of raltegravir and lamivudine after administration of MK-0518B (Formulation #6) and coadministration of the marketed Isentress 400 mg and Efavir 150 mg tablets.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 September 2011
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	Canada: 24
Worldwide total number of subjects	24
EEA total number of subjects	0

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study population included non-smoking, male and female volunteers from 18 to 55 years of age, with a BMI $\leq 31\text{kg/m}^2$, who were judged to be healthy based on a medical history, ECG, laboratory evaluation and physical examination and vital signs measurements. Twenty-four (24) male and female participants met all selection criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: Isentress™ + Epivir™ then MK-0518B

Arm description:

Participants received single doses of co-administered Isentress™ 400 mg and Epivir™ 150 mg in Period 1 then a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 2.

Arm type	Experimental
Investigational medicinal product name	raltegravir
Investigational medicinal product code	
Other name	Isentress™
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Isentress™ (raltegravir) 400 mg tablets were administered with 240 mL water after a fast of at least 10 hours.

Investigational medicinal product name	lamivudine
Investigational medicinal product code	
Other name	Epivir™
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Epivir™ (lamivudine) 150 mg tablets were administered with 240 mL water after a fast of at least 10 hours

Investigational medicinal product name	MK-0518B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

MK-0518B 300 mg reformulated raltegravir / 150 mg lamivudine monolithic tablets were administered with 240 mL water after a fast of at least 10 hours.

Arm title	Sequence 2: MK-0518B then Isentress™ + Epivir™
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Arm description:

Participants received a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 1 then single doses of co-administered Isentress™ 400 mg and Epivir™ 150 mg in Period 2.

Arm type	Experimental
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Investigational medicinal product name	raltegravir
Investigational medicinal product code	
Other name	Isentress™
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Isentress™ (raltegravir) 400 mg tablets were administered with 240 mL water after a fast of at least 10 hours.

Investigational medicinal product name	lamivudine
Investigational medicinal product code	
Other name	Epivir™
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Epivir™ (lamivudine) 150 mg tablets were administered with 240 mL water after a fast of at least 10 hours

Investigational medicinal product name	MK-0518B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

MK-0518B 300 mg reformulated raltegravir / 150 mg lamivudine monolithic tablets were administered with 240 mL water after a fast of at least 10 hours.

Number of subjects in period 1	Sequence 1: Isentress™ + Epivir™ then MK- 0518B	Sequence 2: MK- 0518B then Isentress™ + Epivir™
Started	12	12
Completed	12	10
Not completed	0	2
Adverse event, non-fatal	-	1
Protocol deviation	-	1

Period 2

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Sequence 1: Isentress™ + Efavir™ then MK-0518B
Arm description:	
Participants received single doses of co-administered Isentress™ 400 mg and Efavir™ 150 mg in Period 1 then a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 2.	
Arm type	Experimental
Investigational medicinal product name	raltegravir
Investigational medicinal product code	
Other name	Isentress(TM)
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Isentress™ (raltegravir) 400 mg tablets were administered with 240 mL water after a fast of at least 10 hours.	
Investigational medicinal product name	lamivudine
Investigational medicinal product code	
Other name	Efavir(TM)
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Efavir™ (lamivudine) 150 mg tablets were administered with 240 mL water after a fast of at least 10 hours	
Investigational medicinal product name	MK-0518B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
MK-0518B 300 mg reformulated raltegravir / 150 mg lamivudine monolithic tablets were administered with 240 mL water after a fast of at least 10 hours.	
Arm title	Sequence 2: MK-0518B then Isentress™ + Efavir™
Arm description:	
Participants received a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 1 then single doses of co-administered Isentress™ 400 mg and Efavir™ 150 mg in Period 2.	
Arm type	Experimental
Investigational medicinal product name	raltegravir
Investigational medicinal product code	
Other name	Isentress(TM)
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Isentress™ (raltegravir) 400 mg tablets were administered with 240 mL water after a fast of at least 10 hours.	
Investigational medicinal product name	lamivudine
Investigational medicinal product code	
Other name	Efavir(TM)
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Efavir™ (lamivudine) 150 mg tablets were administered with 240 mL water after a fast of at least 10 hours	
Investigational medicinal product name	MK-0518B
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

MK-0518B 300 mg reformulated raltegravir / 150 mg lamivudine monolithic tablets were administered with 240 mL water after a fast of at least 10 hours.

Number of subjects in period 2	Sequence 1: Isentress™ + Epivir™ then MK- 0518B	Sequence 2: MK- 0518B then Isentress™ + Epivir™
Started	12	10
Completed	12	10

Baseline characteristics

Reporting groups

Reporting group title	Period 1
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Reporting group description:

All participants who were enrolled in the study.

Reporting group values	Period 1	Total	
Number of subjects	24	24	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	36		
standard deviation	± 9	-	
Gender categorical			
Units: Subjects			
Female	10	10	
Male	14	14	

End points

End points reporting groups

Reporting group title	Sequence 1: Isentress™ + Efavir™ then MK-0518B
Reporting group description: Participants received single doses of co-administered Isentress™ 400 mg and Efavir™ 150 mg in Period 1 then a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 2.	
Reporting group title	Sequence 2: MK-0518B then Isentress™ + Efavir™
Reporting group description: Participants received a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 1 then single doses of co-administered Isentress™ 400 mg and Efavir™ 150 mg in Period 2.	
Reporting group title	Sequence 1: Isentress™ + Efavir™ then MK-0518B
Reporting group description: Participants received single doses of co-administered Isentress™ 400 mg and Efavir™ 150 mg in Period 1 then a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 2.	
Reporting group title	Sequence 2: MK-0518B then Isentress™ + Efavir™
Reporting group description: Participants received a single dose of MK-0518B (300 mg raltegravir/150 mg lamivudine) in Period 1 then single doses of co-administered Isentress™ 400 mg and Efavir™ 150 mg in Period 2.	
Subject analysis set title	Isentress™ + Efavir™
Subject analysis set type	Per protocol
Subject analysis set description: Participants who received Isentress™ + Efavir™ and completed the study.	
Subject analysis set title	MK-0518B
Subject analysis set type	Per protocol
Subject analysis set description: Participants who received MK-0518B and completed the study.	

Primary: The area under the raltegravir concentration vs time curve from time zero to infinity (AUC_{0-∞})

End point title	The area under the raltegravir concentration vs time curve from time zero to infinity (AUC _{0-∞})
End point description: Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Primary
End point timeframe: Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Efavir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng*h/mL				
geometric mean (confidence interval 95%)	6756.58 (4815.4 to 9480.3)	7210.2 (6221.15 to 8356.47)		

Statistical analyses

Statistical analysis title	MK-0518B vs. Isentress™ + Epivir™
Statistical analysis description: Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Epivir™. GMR = (MK-0518B/Isentress™ + Epivir™)	
Comparison groups	Isentress™ + Epivir™ v MK-0518B
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	106.71
Confidence interval	
level	90 %
sides	2-sided
lower limit	83.05
upper limit	137.11

Primary: Maximum concentration (Cmax) of raltegravir

End point title	Maximum concentration (Cmax) of raltegravir
End point description: Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Primary
End point timeframe: Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Epivir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng/mL				
geometric mean (confidence interval 95%)	1831.23 (1176.95 to 2849.21)	2740.89 (2153.89 to 3487.85)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Epivir™
Statistical analysis description: Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same	

participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Epivir™. GMR = (MK-0518B/Isentress™ + Epivir™)

Comparison groups	Isentress™ + Epivir™ v MK-0518B
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	149.68
Confidence interval	
level	90 %
sides	2-sided
lower limit	105.86
upper limit	211.62

Primary: The area under the lamivudine concentration vs time curve of from time zero to infinity (AUC0-∞)

End point title	The area under the lamivudine concentration vs time curve of from time zero to infinity (AUC0-∞)
End point description:	
Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Primary
End point timeframe:	
Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Epivir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng*h/mL				
geometric mean (confidence interval 95%)	5879.3 (5421.8 to 6375.4)	6107.2 (5652.1 to 6598.9)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Epivir™
Statistical analysis description:	
Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Epivir™. GMR = (MK-0518B/Isentress™ + Epivir™)	
Comparison groups	Isentress™ + Epivir™ v MK-0518B

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	103.88
Confidence interval	
level	90 %
sides	2-sided
lower limit	97.64
upper limit	110.51

Primary: Maximum concentration (Cmax) of lamivudine

End point title	Maximum concentration (Cmax) of lamivudine
End point description: Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Primary
End point timeframe: Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Epivir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng/mL				
geometric mean (confidence interval 95%)	1205.7 (1057.6 to 1374.4)	1362.1 (1188.9 to 1560.6)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Epivir™
Statistical analysis description: Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Epivir™. GMR = (MK-0518B/Isentress™ + Epivir™)	
Comparison groups	Isentress™ + Epivir™ v MK-0518B

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	112.98
Confidence interval	
level	90 %
sides	2-sided
lower limit	102.3
upper limit	124.77

Secondary: The area under the raltegravir concentration vs time curve of from time zero to the last sampling time with quantifiable analyte (AUC0-t)

End point title	The area under the raltegravir concentration vs time curve of from time zero to the last sampling time with quantifiable analyte (AUC0-t)
End point description:	
Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Secondary
End point timeframe:	
Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Efavir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng*h/mL				
geometric mean (confidence interval 95%)	6565.66 (4652.46 to 9265.61)	7061.36 (6094.57 to 8181.5)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Efavir™
Statistical analysis description:	
Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Efavir™. GMR = (MK-0518B/Isentress™ + Efavir™)	
Comparison groups	Isentress™ + Efavir™ v MK-0518B

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	107.55
Confidence interval	
level	90 %
sides	2-sided
lower limit	82.91
upper limit	139.5

Secondary: Concentration of raltegravir at time 12 hours (C12)

End point title	Concentration of raltegravir at time 12 hours (C12)
End point description:	
Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Secondary
End point timeframe:	
Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Epivir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng/mL				
geometric mean (confidence interval 95%)	28.04 (22.81 to 34.47)	25.41 (20.77 to 31.1)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Epivir™
Statistical analysis description:	
Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Epivir™. GMR = (MK-0518B/Isentress™ + Epivir™)	
Comparison groups	Isentress™ + Epivir™ v MK-0518B
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	90.63

Confidence interval	
level	90 %
sides	2-sided
lower limit	76.9
upper limit	106.81

Secondary: The area under the lamivudine concentration vs time curve from time zero to the last sampling time with quantifiable analyte (AUC0-t)

End point title	The area under the lamivudine concentration vs time curve from time zero to the last sampling time with quantifiable analyte (AUC0-t)
End point description: Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose.	
End point type	Secondary
End point timeframe: Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Efavir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng*h/mL				
geometric mean (confidence interval 95%)	5655.4 (5182.1 to 6171.9)	6019 (5423.2 to 6680.2)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Efavir™
Statistical analysis description: Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Efavir™. GMR = (MK-0518B/Isentress™ + Efavir™)	
Comparison groups	Isentress™ + Efavir™ v MK-0518B
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	Geometric mean ratio
Point estimate	106.43

Confidence interval	
level	90 %
sides	2-sided
lower limit	99.77
upper limit	113.53

Secondary: Concentration of lamivudine at time 12 hours (C12)

End point title	Concentration of lamivudine at time 12 hours (C12)
End point description: Blood samples for analysis of pharmacokinetic parameters were collected prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	
End point type	Secondary
End point timeframe: Predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, and 48 hours postdose	

End point values	Isentress™ + Epivir™	MK-0518B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	24		
Units: ng/mL				
geometric mean (confidence interval 95%)	68.7 (59.7 to 79)	70.6 (61.7 to 80.8)		

Statistical analyses

Statistical analysis title	MK-0518B vs Isentress™ + Epivir™
Statistical analysis description: Treatment differences were compared using a linear mixed effect model containing period and treatment as fixed effects. An unstructured covariance matrix was used to allow for unequal treatment variances and to model the correlation between the two treatment measurements within each subject. The same participants and number (n=24) were to have received both treatments but due to dropouts, n=24 received MK-0518B and n=22 received Isentress™ + Epivir™. GMR = (MK-0518B/Isentress™ + Epivir™)	
Comparison groups	Isentress™ + Epivir™ v MK-0518B
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
Method	Mixed models analysis
Parameter estimate	geometric mean ratio
Point estimate	102.89
Confidence interval	
level	90 %
sides	2-sided
lower limit	97.76
upper limit	108.28

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Predose to 14 days following the last dose of study drug (approximately 20 days).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	Isentress™ + Epivir™
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Reporting group description: -

Reporting group title	MK-0518B
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Reporting group description: -

Serious adverse events	Isentress™ + Epivir™	MK-0518B	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	0 / 24 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Isentress™ + Epivir™	MK-0518B	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 22 (18.18%)	3 / 24 (12.50%)	
Investigations			
Blood Glucose Increased			
subjects affected / exposed	2 / 22 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	2	0	
Blood creatine increased			
subjects affected / exposed	0 / 22 (0.00%)	3 / 24 (12.50%)	
occurrences (all)	0	3	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 22 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	2	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