A Study to Determine the Safety and Efficacy of Once Daily Raltegravir Compared to Twice Daily Raltegravir (MK-0518-071)

This study has been terminated.

(Primary efficacy analysis at Week 48 did not demonstrate non-inferiority of raltegravir 800 mg once daily versus raltegravir 400 mg twice daily)

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00745823

First received: September 2, 2008
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

Purpose

A study to evaluate the safety, tolerability and efficacy of once daily Raltegravir compared to twice daily raltegravir when each is given in combination with TRUVADA™ in treatment-naïve human immunodeficiency virus (HIV)-infected patients.

Condition	Intervention	Phase
HIV	Drug: Comparator: Raltegravir 400 mg b.i.d. Drug: Experimental: Raltegravir 800 mg q.d. Drug: TRUVADA™	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Once Daily Raltegravir (MK0518) Versus Twice Daily Raltegravir, Each in Combination With TRUVADA™, in Treatment-Naïve HIV Infected Patients

Resource links provided by NLM:

MedlinePlus related topics: HIV/AIDS

Drug Information available for: Raltegravir Truvada Raltegravir potassium

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Participants With HIV Ribonucleic Acid (RNA) <50 Copies/mL at 48 Weeks [Time Frame: Week 48] [Designated as safety issue: No]
- Number of Participants With One or More Adverse Events at 48 Weeks [Time Frame: Week 48] [Designated as safety issue: Yes]
- Number of Participants Who Discontinued Due to an Adverse Event at 48 Weeks [Time Frame: Week 48] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Number of Participants With HIV Ribonucleic Acid (RNA) <400 Copies/mL at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: No]
- Mean Change From Baseline to Week 48 in CD4 Cell Count [Time Frame: Baseline and Week 48] [Designated as safety issue: No]
- Number of Participants With HIV RNA <50 Copies/mL at 96 Weeks [Time Frame: Week 96] [Designated as safety issue: No]

  As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.

- Number of Participants With HIV RNA <400 Copies/mL at 96 Weeks [Time Frame: Week 96] [Designated as safety issue: No]

  As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.

- Mean Change From Baseline to Week 96 in CD4 Cell Count [Time Frame: Baseline and Week 96] [Designated as safety issue: No]

  As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.

- Number of Participants With One or More Adverse Events at 96 Weeks [Time Frame: Week 96] [Designated as safety issue: Yes]

  As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.

- Number of Participants Who Discontinued Due to an Adverse Event at 96 Weeks [Time Frame: Week 96] [Designated as safety issue: Yes]

  As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.

Enrollment:	775
Study Start Date:	September 2008
Study Completion Date:	May 2011
Primary Completion Date:	October 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Raltegravir 400 mg b.i.d.	Drug: Comparator: Raltegravir 400 mg b.i.d. Raltegravir 400 mg tablet by mouth (PO) twice daily (b.i.d.) + two raltegravir placebo tablets + one tablet of TRUVADA™ once daily (q.d.) Other Name: ISENTRESS™ Drug: TRUVADA™ One tablet TRUVADA™ q.d. (fixed combination 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate)
Experimental: Raltegravir 800 mg q.d.	Drug: Experimental: Raltegravir 800 mg q.d. Raltegravir 800 mg tablet PO q.d. + two raltegravir placebo tablets + one tablet TRUVADA™ q.d. Other Name: ISENTRESS™ Drug: TRUVADA™ One tablet TRUVADA™ q.d. (fixed combination 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate)

Detailed Description:

Following the 96-week double-blind study period (MK0518-071)(NCT00745823), subjects may enroll in an extension study (MK0518-071-10) (NCT00745823). From weeks 96 to 120, subjects' treatment assignments will remain as in the base study.

From week 120 to 240, all subjects will receive open-label raltegravir (800 mg, once daily) in combination with TRUVADA™.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patient is male or female 18 years of age or older
- Patient is HIV positive
- Patient is naïve to antiretroviral therapy (ART) or has received less than 7 days total of any ART

Extension Study:

- The planned extension study did not take place as the study was terminated after the Week 48 analysis.

Exclusion Criteria:

- Patient is a user of recreational or illicit drugs or has had a recent history (within the last year) of drug or alcohol abuse or dependence
- Patient has documented resistance to tenofovir or emtricitabine
- Patient is currently participating or has participated in a study with an investigational compound or device within 45 days of signing informed consent
- Patient is pregnant or breastfeeding, or expecting to conceive

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00745823

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

No publications provided by Merck Sharp & Dohme Corp.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Eron JJ Jr, Rockstroh JK, Reynes J, Andrade-Villanueva J, Ramalho-Madruga JV, Bekker LG, Young B, Katlama C, Gatell-Artigas JM, Arribas JR, Nelson M, Campbell H, Zhao J, Rodgers AJ, Rizk ML, Wenning L, Miller MD, Hazuda D, DiNubile MJ, Leavitt R, Isaacs R, Robertson MN, Sklar P, Nguyen BY; QDMRK Investigators. Raltegravir once daily or twice daily in previously untreated patients with HIV-1: a randomised, active-controlled, phase 3 non-inferiority trial. Lancet Infect Dis. 2011 Dec;11(12):907-15. doi: 10.1016/S1473-3099(11)70196-7. Epub 2011 Sep 18. Erratum in: Lancet Infect Dis. 2011 Dec;11(12):895. Dosage error in article text.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00745823 History of Changes
Other Study ID Numbers: **0518-071** 2008_543 CTRI/2009/091/000145
Study First Received: September 2, 2008
Results First Received: March 6, 2012
Last Updated: October 1, 2015
Health Authority: United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
HIV Infections

Treatment Naïve

ClinicalTrials.gov processed this record on March 10, 2016

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This study has been terminated.

(Primary efficacy analysis at Week 48 did not demonstrate non-inferiority of raltegravir 800 mg once daily versus raltegravir 400 mg twice daily)

Sponsor:
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Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00745823

First received: September 2, 2008
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

Results First Received: March 6, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	HIV
Interventions:	Drug: Comparator: Raltegravir 400 mg b.i.d. Drug: Experimental: Raltegravir 800 mg q.d. Drug: TRUVADA™

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Participant Flow: Overall Study

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.
STARTED	**386**	**389**
TREATED Week 0 - 96	**382**	**388**
COMPLETED	**1**	**3**
NOT COMPLETED	**385**	**386**
Adverse Event	**5**	**3**
Lack of Efficacy	**20**	**6**
Lost to Follow-up	**10**	**11**
Physician Decision	**10**	**5**
Pregnancy	**0**	**4**
Withdrawal by Subject	**14**	**8**
Study Terminated by Sponsor	**326**	**349**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks
Total	Total of all reporting groups

Baseline Measures

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.	Total
Number of Participants [units: participants]	**386**	**389**	**775**
Age, Customized			

[units: participants]			
Between 18 and 64 years	**382**	**382**	**764**
>=64 years	**4**	**7**	**11**
Gender [units: participants]			
Female	**68**	**90**	**158**
Male	**318**	**299**	**617**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With HIV Ribonucleic Acid (RNA) <50 Copies/mL at 48 Weeks [Time Frame: Week 48]

Measure Type	Primary
Measure Title	Number of Participants With HIV Ribonucleic Acid (RNA) <50 Copies/mL at 48 Weeks
Measure Description	No text entered.
Time Frame	Week 48
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data were analyzed for all participants treated with study drug. Participants who did not complete the study were treated as treatment failures.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**
Number of Participants Analyzed [units: participants]	**382**	**386**
Number of Participants With HIV Ribonucleic Acid (RNA) <50 Copies/mL at 48 Weeks [units: Participants]	**318**	**343**

Statistical Analysis 1 for Number of Participants With HIV Ribonucleic Acid (RNA) <50 Copies/mL at 48 Weeks

Groups [1]	All groups
[2]	Yes

Non-Inferiority/Equivalence Test	
Method [3]	Miettinen and Nurminen
P Value [4]	0.044
Mean Difference (Final Values) [5]	-5.7
95% Confidence Interval	-10.7 to -0.83

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The 800 mg q.d. dosage was considered non-inferior to 400 mg b.i.d. if the lower bound of the 2-sided exact 95% CI for difference in response rate remained above -10%.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	No text entered.

2. Primary: Number of Participants With One or More Adverse Events at 48 Weeks [Time Frame: Week 48]

Measure Type	Primary
Measure Title	Number of Participants With One or More Adverse Events at 48 Weeks
Measure Description	No text entered.
Time Frame	Week 48
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data were analyzed for all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**

Number of Participants Analyzed [units: participants]	**382**	**388**
Number of Participants With One or More Adverse Events at 48 Weeks [units: Participants]	**331**	**337**

Statistical Analysis 1 for Number of Participants With One or More Adverse Events at 48 Weeks

Groups [1]	All groups
Method [2]	Miettinen and Nurminen
Mean Difference (Final Values) [3]	-0.2
95% Confidence Interval	-5.0 to 4.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Other relevant estimation information:
	No text entered.

3. Primary: Number of Participants Who Discontinued Due to an Adverse Event at 48 Weeks [Time Frame: Week 48]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinued Due to an Adverse Event at 48 Weeks
Measure Description	No text entered.
Time Frame	Week 48
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data were analyzed for all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**

Number of Participants Analyzed [units: participants]	**382**	**388**
Number of Participants Who Discontinued Due to an Adverse Event at 48 Weeks [units: Participants]	**4**	**3**

Statistical Analysis 1 for Number of Participants Who Discontinued Due to an Adverse Event at 48 Weeks

Groups [1]	All groups
Mean Difference (Final Values) [2]	0.3
95% Confidence Interval	-1.3 to 2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	No text entered.

4. Secondary: Number of Participants With HIV Ribonucleic Acid (RNA) <400 Copies/mL at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With HIV Ribonucleic Acid (RNA) <400 Copies/mL at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data were analyzed for all participants treated with study drug. Participants who did not complete the study were treated as treatment failures.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**
Number of Participants Analyzed [units: participants]	**382**	**386**
Number of Participants With HIV Ribonucleic Acid (RNA) <400 Copies/mL at 48 Weeks [units: Participants]	**338**	**361**

Statistical Analysis 1 for Number of Participants With HIV Ribonucleic Acid (RNA) <400 Copies/mL at 48 Weeks

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Miettinen and Nurminen
P Value [4]	0.011
Mean Difference (Final Values) [5]	-5.1
95% Confidence Interval	-9.29 to -1.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The 800 mg q.d. dosage was considered non-inferior to 400 mg b.i.d. if the lower bound of the 2-sided exact 95% CI for difference in response rate remained above -10%.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	No text entered.

5. Secondary: Mean Change From Baseline to Week 48 in CD4 Cell Count [Time Frame: Baseline and Week 48]

Measure Type	Secondary
Measure Title	Mean Change From Baseline to Week 48 in CD4 Cell Count
Measure Description	No text entered.
Time Frame	Baseline and Week 48
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data were analyzed for all participants treated with study drug. Baseline values were carried forward for participants who discontinued treatment due to lack of efficacy.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks

Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.
Number of Participants Analyzed [units: participants]	**382**	**386**
Mean Change From Baseline to Week 48 in CD4 Cell Count [units: cells/mm^3] Mean (95% Confidence Interval)	**209.76 (194.6 to 224.9)**	**196.20 (181.8 to 210.6)**

Statistical Analysis 1 for Mean Change From Baseline to Week 48 in CD4 Cell Count

Groups [1]	All groups
Method [2]	t-test, 2 sided
Mean Difference (Net) [3]	13.56
95% Confidence Interval	-7.29 to 34.40

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Other relevant estimation information:
	No text entered.

6. Secondary: Number of Participants With HIV RNA <50 Copies/mL at 96 Weeks [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With HIV RNA <50 Copies/mL at 96 Weeks
Measure Description	As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.
Time Frame	Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Week 96 data analysis was not performed.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet

	of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With HIV RNA <50 Copies/mL at 96 Weeks		

No statistical analysis provided for Number of Participants With HIV RNA <50 Copies/mL at 96 Weeks

7. Secondary: Number of Participants With HIV RNA <400 Copies/mL at 96 Weeks [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With HIV RNA <400 Copies/mL at 96 Weeks
Measure Description	As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.
Time Frame	Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Week 96 data analysis was not performed.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With HIV RNA <400 Copies/mL at 96 Weeks		

No statistical analysis provided for Number of Participants With HIV RNA <400 Copies/mL at 96 Weeks

8. Secondary: Mean Change From Baseline to Week 96 in CD4 Cell Count [Time Frame: Baseline and Week 96]

Measure Type	Secondary
Measure Title	Mean Change From Baseline to Week 96 in CD4 Cell Count
Measure Description	As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.
Time Frame	Baseline and Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Week 96 data analysis was not performed.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg PO q.d. plus placebo to raltegravir PO b.i.d. plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg b.i.d. administered with TRUVADA™

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**
Number of Participants Analyzed [units: participants]	**0**	**0**
Mean Change From Baseline to Week 96 in CD4 Cell Count		

No statistical analysis provided for Mean Change From Baseline to Week 96 in CD4 Cell Count

9. Secondary: Number of Participants With One or More Adverse Events at 96 Weeks [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With One or More Adverse Events at 96 Weeks
Measure Description	As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.
Time Frame	Week 96
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description

Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With One or More Adverse Events at 96 Weeks		

No statistical analysis provided for Number of Participants With One or More Adverse Events at 96 Weeks

10. Secondary: Number of Participants Who Discontinued Due to an Adverse Event at 96 Weeks [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants Who Discontinued Due to an Adverse Event at 96 Weeks
Measure Description	As the study was terminated after the 48-week analysis, the planned secondary analyses for Week 96 were not performed.
Time Frame	Week 96
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Measured Values

	Raltegravir 800 mg q.d.	**Raltegravir 400 mg b.i.d.**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants Who Discontinued Due to an Adverse Event at 96 Weeks		

No statistical analysis provided for Number of Participants Who Discontinued Due to an Adverse Event at 96 Weeks

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Overall Study
Additional Description	No text entered.

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Serious Adverse Events

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.
Total, serious adverse events		
# participants affected / at risk	**29/382 (7.59%)**	**46/388 (11.86%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Lymphadenitis † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Lymphadenopathy † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Retroperitoneal lymphadenopathy † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Thrombocytopenia † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Cardiac disorders		
Atrial fibrillation † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Pericarditis † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Anal fistula † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**

# events	0	1
Diarrhoea † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Inguinal hernia † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Proctalgia † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Vomiting † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
General disorders		
Chest pain † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Pyrexia † 1		
# participants affected / at risk	0/382 (0.00%)	4/388 (1.03%)
# events	0	4
Hepatobiliary disorders		
Cholecystitis acute † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Cholecystitis chronic † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Cholelithiasis † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Hepatitis † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Immune system disorders		
Immune reconstitution syndrome † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Infections and infestations		
Abscess intestinal † 1		
# participants affected / at risk	1/382 (0.26%)	0/388 (0.00%)
# events	1	0
Abscess jaw † 1		
# participants affected / at risk	1/382 (0.26%)	0/388 (0.00%)
# events	1	0

Anogenital warts † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Appendicitis † 1		
# participants affected / at risk	**2/382 (0.52%)**	**1/388 (0.26%)**
# events	**2**	**1**
Cytomegalovirus infection † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Diarrhoea infectious † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Eye infection syphilitic † 1		
# participants affected / at risk	**1/382 (0.26%)**	**1/388 (0.26%)**
# events	**1**	**1**
Gastroenteritis † 1		
# participants affected / at risk	**0/382 (0.00%)**	**2/388 (0.52%)**
# events	**0**	**2**
Histoplasmosis † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Meningitis aseptic † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Meningitis cryptococcal † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**2**	**0**
Meningitis viral † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Mycobacterium avium complex infection † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Orchitis † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Perirectal abscess † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Pneumonia † 1		
# participants affected / at risk	**1/382 (0.26%)**	**1/388 (0.26%)**
# events	**1**	**1**
Pneumonia pneumococcal † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
† 1		

Post procedural pneumonia		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Sepsis [† 1]		
# participants affected / at risk	**0/382 (0.00%)**	**2/388 (0.52%)**
# events	**0**	**2**
Shigella infection [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**1/388 (0.26%)**
# events	**1**	**1**
Injury, poisoning and procedural complications		
Forearm fracture [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Meniscus lesion [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Multiple drug overdose [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Muscle injury [† 1]		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Penis injury [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Tibia fracture [† 1]		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Wrist fracture [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Metabolism and nutrition disorders		
Obesity [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Anal cancer stage 0 [† 1]		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Basal cell carcinoma [† 1]		
# participants affected / at risk	**0/382 (0.00%)**	**2/388 (0.52%)**
# events	**0**	**2**
Bowen's disease [† 1]		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**

# events	0	1
Burkitt's lymphoma † 1		
# participants affected / at risk	0/382 (0.00%)	2/388 (0.52%)
# events	0	2
Colon cancer † 1		
# participants affected / at risk	1/382 (0.26%)	0/388 (0.00%)
# events	1	0
Hodgkin's disease † 1		
# participants affected / at risk	0/382 (0.00%)	2/388 (0.52%)
# events	0	2
Kaposi's sarcoma AIDS related † 1		
# participants affected / at risk	3/382 (0.79%)	3/388 (0.77%)
# events	3	3
Leiomyoma † 1		
# participants affected / at risk	1/382 (0.26%)	0/388 (0.00%)
# events	1	0
Lymphoma † 1		
# participants affected / at risk	1/382 (0.26%)	0/388 (0.00%)
# events	1	0
Prostate cancer † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Renal cell carcinoma † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Retroperitoneal neoplasm metastatic † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Skin cancer † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	2
Nervous system disorders		
Cerebral haemorrhage † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Convulsion † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1
Transient ischaemic attack † 1		
# participants affected / at risk	1/382 (0.26%)	0/388 (0.00%)
# events	1	0
Psychiatric disorders		
Abnormal behaviour † 1		
# participants affected / at risk	0/382 (0.00%)	1/388 (0.26%)
# events	0	1

Panic attack † 1		
# participants affected / at risk	**2/382 (0.52%)**	**0/388 (0.00%)**
# events	**2**	**0**
Suicidal ideation † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Suicide attempt † 1		
# participants affected / at risk	**1/382 (0.26%)**	**4/388 (1.03%)**
# events	**1**	**4**
Renal and urinary disorders		
Nephrolithiasis † 1		
# participants affected / at risk	**1/382 (0.26%)**	**1/388 (0.26%)**
# events	**1**	**1**
Renal colic † 1		
# participants affected / at risk	**2/382 (0.52%)**	**0/388 (0.00%)**
# events	**3**	**0**
Renal failure acute † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Reproductive system and breast disorders		
Amenorrhoea † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Epididymitis † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Respiratory, thoracic and mediastinal disorders		
Pleural effusion † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Skin and subcutaneous tissue disorders		
Hypoaesthesia facial † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Psoriasis † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**1**
Vascular disorders		
Aortic aneurysm † 1		
# participants affected / at risk	**1/382 (0.26%)**	**0/388 (0.00%)**
# events	**1**	**0**
Deep vein thrombosis † 1		
# participants affected / at risk	**0/382 (0.00%)**	**1/388 (0.26%)**
# events	**0**	**2**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Overall Study
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Raltegravir 800 mg q.d.	Raltegravir 800 mg by mouth (PO) once daily (q.d.) plus placebo to raltegravir PO twice daily (b.i.d.) plus one tablet of TRUVADA™ for 96 weeks
Raltegravir 400 mg b.i.d.	Raltegravir 400 mg PO b.i.d. plus placebo to raltegravir PO q.d. plus one tablet of TRUVADA™ for 96 weeks

Other Adverse Events

	Raltegravir 800 mg q.d.	Raltegravir 400 mg b.i.d.
Total, other (not including serious) adverse events		
# participants affected / at risk	**287/382 (75.13%)**	**282/388 (72.68%)**
Blood and lymphatic system disorders		
Lymphadenopathy † 1		
# participants affected / at risk	**22/382 (5.76%)**	**21/388 (5.41%)**
# events	**23**	**23**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**13/382 (3.40%)**	**21/388 (5.41%)**
# events	**14**	**27**
Diarrhoea † 1		
# participants affected / at risk	**70/382 (18.32%)**	**70/388 (18.04%)**
# events	**81**	**87**
Nausea † 1		
# participants affected / at risk	**41/382 (10.73%)**	**54/388 (13.92%)**
# events	**47**	**57**
Vomiting † 1		
# participants affected / at risk	**24/382 (6.28%)**	**25/388 (6.44%)**
# events	**29**	**36**
General disorders		
† 1		

Fatigue		
# participants affected / at risk	**25/382 (6.54%)**	**27/388 (6.96%)**
# events	**28**	**30**
Pyrexia † 1		
# participants affected / at risk	**19/382 (4.97%)**	**26/388 (6.70%)**
# events	**23**	**35**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**31/382 (8.12%)**	**28/388 (7.22%)**
# events	**32**	**34**
Gastroenteritis † 1		
# participants affected / at risk	**21/382 (5.50%)**	**14/388 (3.61%)**
# events	**23**	**18**
Influenza † 1		
# participants affected / at risk	**25/382 (6.54%)**	**36/388 (9.28%)**
# events	**28**	**40**
Nasopharyngitis † 1		
# participants affected / at risk	**40/382 (10.47%)**	**54/388 (13.92%)**
# events	**51**	**70**
Sinusitis † 1		
# participants affected / at risk	**16/382 (4.19%)**	**30/388 (7.73%)**
# events	**17**	**36**
Upper respiratory tract infection † 1		
# participants affected / at risk	**49/382 (12.83%)**	**54/388 (13.92%)**
# events	**64**	**70**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**19/382 (4.97%)**	**25/388 (6.44%)**
# events	**22**	**32**
Back pain † 1		
# participants affected / at risk	**23/382 (6.02%)**	**22/388 (5.67%)**
# events	**28**	**25**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**36/382 (9.42%)**	**29/388 (7.47%)**
# events	**39**	**35**
Headache † 1		
# participants affected / at risk	**58/382 (15.18%)**	**62/388 (15.98%)**
# events	**70**	**87**
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	**22/382 (5.76%)**	**23/388 (5.93%)**
# events	**22**	**25**
Insomnia † 1		
# participants affected / at risk	**18/382 (4.71%)**	**22/388 (5.67%)**

# events	18	22
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	38/382 (9.95%)	30/388 (7.73%)
# events	40	41
Oropharyngeal pain † 1		
# participants affected / at risk	15/382 (3.93%)	20/388 (5.15%)
# events	19	23
Skin and subcutaneous tissue disorders		
Rash † 1		
# participants affected / at risk	23/382 (6.02%)	23/388 (5.93%)
# events	26	27
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	11/382 (2.88%)	22/388 (5.67%)
# events	11	22

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 14.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

The study was terminated before the 96-week efficacy analysis. Adverse event data were collected for the entire treatment period up to a maximum of Week 108, which defines the Overall Study period.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Twenty-four months after completion of this study or after publication of the multicenter results, an investigator may publish the results for their study site independently. The sponsor must have the opportunity to review all proposed publications or presentations regarding the study 60 days before submission.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1- 800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

No publications provided by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Eron JJ Jr, Rockstroh JK, Reynes J, Andrade-Villanueva J, Ramalho-Madruga JV, Bekker LG, Young B, Katlama C, Gatell-Artigas JM, Arribas JR, Nelson M, Campbell H, Zhao J, Rodgers AJ, Rizk ML, Wenning L, Miller MD, Hazuda D, DiNubile MJ, Leavitt R, Isaacs R, Robertson MN, Sklar P, Nguyen BY; QDMRK Investigators. Raltegravir once daily or twice daily in previously untreated patients with HIV-1: a randomised, active-controlled, phase 3 non-inferiority trial. Lancet Infect Dis. 2011 Dec;11(12):907-15. doi: 10.1016/S1473-3099(11)70196-7. Epub 2011 Sep 18. Erratum in: Lancet Infect Dis. 2011 Dec;11(12):895. Dosage error in article text.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00745823 History of Changes
Other Study ID Numbers:	**0518-071** 2008_543 (Other Identifier: Merck Registration Number) CTRI/2009/091/000145 (Registry Identifier: CTRI)
Study First Received:	September 2, 2008
Results First Received:	March 6, 2012
Last Updated:	October 1, 2015
Health Authority:	United States: Food and Drug Administration

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