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Trial record **1 of 1** for: CR013159

Previous Study | Return to List | Next Study

Treatment Simplification by Darunavir/Ritonavir 800/100 mg Once a Day Versus a Triple Combination Therapy With Darunavir/Ritonavir (MONET)

This study has been completed.

Sponsor:
Janssen-Cilag International NV

Information provided by (Responsible Party):
Janssen-Cilag International NV

ClinicalTrials.gov Identifier:
NCT00458302

First received: April 6, 2007
Last updated: December 14, 2012
Last verified: December 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: February 4, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	HIV Infections AIDS Virus Human Immunodeficiency Virus Acquired Immunodeficiency Syndrome Virus
Intervention:	Drug: darunavir (DRV, TMC114)

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
xxxxx

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
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Participant Flow: Overall Study

	DRV/r+2NRTIs	DRV/r
STARTED	**129**	**127**

COMPLETED	**109**	**103**
NOT COMPLETED	**20**	**24**
Adverse Event	**4**	**14**
Pregnancy	**2**	**1**
Protocol Violation	**0**	**2**
Withdrawal by Subject	**6**	**4**
Inc/Exc Criteria Not Met	**1**	**1**
Study Termination By Sponsor	**1**	**0**
Lost to Follow-up	**2**	**0**
Unknown	**4**	**2**

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
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks
Total	Total of all reporting groups

Baseline Measures

	DRV/r+2NRTIs	DRV/r	Total
Number of Participants [units: participants]	**129**	**127**	**256**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**128**	**125**	**253**
>=65 years	**1**	**2**	**3**
Age [units: years] Mean (Standard Deviation)	**44.1 (9.74)**	**43.4 (9.14)**	**43.7 (9.43)**
Gender [units: participants]			
Female	**22**	**28**	**50**
Male	**107**	**99**	**206**
Region of Enrollment [units: participants]			
AUSTRIA	**9**	**7**	**16**
BELGIUM	**12**	**12**	**24**

DENMARK	14	14	28
GERMANY	14	14	28
HUNGARY	6	5	11
ISRAEL	1	7	8
ITALY	11	5	16
POLAND	9	20	29
PORTUGAL	7	7	14
RUSSIAN FEDERATION	9	2	11
SPAIN	24	24	48
SWITZERLAND	1	1	2
UNITED KINGDOM	12	9	21
plasma viral load [1] [units: participants]			
< 50	125	118	243
50-400	4	7	11
400-1000	0	0	0
> 1000	0	2	2
CD4+ cell count (absolute count) [units: cells/µl] Median (Full Range)	579.0 (163 to 1888)	571.0 (162 to 1451)	573.5 (162 to 1888)

[1] plasma viral load (HIV-1 RNA copies/ml)

Outcome Measures

Hide All Outcome Measures

1. Primary: Virological Response [Per Protocol (PP) - Time to Loss of Virologic Response (TLOVR), < 50 Copies/ml, Week 48] [Time Frame: Week 48]

Measure Type	Primary
Measure Title	Virological Response [Per Protocol (PP) - Time to Loss of Virologic Response (TLOVR), < 50 Copies/ml, Week 48]
Measure Description	Virological response is defined as the number of patients in the PP population with a plasma viral load < 50 HIV RNA copies/ml at Week 48. Treatment failure was defined as two consecutive HIV RNA levels ≥ 50 copies/mL, or discontinuation of randomised treatment (known as TLOVR). In addition, any switch in background nucleoside reverse transcriptase inhibitors (NRTIs) equaled failure* (referred to as a Switch Equals Failure analysis). *Discontinuations and rechallenge with NRTIs are taken into account until Week 48
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.
PP population: all randomised patients who took study drug, and who did not deviate from the protocol.This excludes 10 patients with major protocol deviations.

Reporting Groups

	Description

DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**123**	**123**
Virological Response [Per Protocol (PP) - Time to Loss of Virologic Response (TLOVR), < 50 Copies/ml, Week 48] [units: participants]	**108**	**106**

Statistical Analysis 1 for Virological Response [Per Protocol (PP) - Time to Loss of Virologic Response (TLOVR), < 50 Copies/ml, Week 48]

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Difference in proportion of response [3]	-1.6
95% Confidence Interval	-10.1 to 6.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Assuming a virologic response rate of 90% at 48 weeks for both treatment arms, 111 patients were required per treatment arm to establish non-inferiority of DRV/r versus triple regimen with a maximum allowable difference of 12%, with a one-sided significance level of p=0.025 and 80% power. To account for a maximum of 10% major protocol violations that would be excluded from the on-protocol analysis, 125 patients were recruited in each treatment arm, so 250 patients in total.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The primary comparison was performed at Week 48. If at Week 48, the lower limit of the 95% two-sided confidence interval of the difference between DRV/r and DRV/r+2NRTIs exceeds -12%, non-inferiority of the DRV/r 800/100 once a day (O.D) monotherapy versus the DRV/r 800/100 mg O.D. plus two NRTIs triple combination therapy was concluded.
[3]	Other relevant estimation information:
	Difference in proportion of response DRV/r minus DRV/r+2NRTIs.

2. Secondary: Virological Response [Intent To Treat (ITT) - TLOVR, < 50 Copies/ml, Week 48] [Time Frame: Week 48]

Measure Type	Secondary
Measure Title	Virological Response [Intent To Treat (ITT) - TLOVR, < 50 Copies/ml, Week 48]
Measure Description	Virological response is defined as the number of patients in the ITT population with a plasma viral load < 50 HIV RNA copies/ml at Week 48. Treatment failure was defined as two consecutive HIV RNA levels ≥ 50 copies/mL, or discontinuation of randomised treatment (known as TLOVR). In addition, any switch in background nucleoside reverse transcriptase inhibitors (NRTIs) equaled failure* (referred to as a Switch Equals Failure analysis). *Discontinuations and rechallenge with NRTIs are taken into account until start of Week 48 window
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.
ITT population: all randomised patients who took study drug, regardless of their compliance with the protocol.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**129**	**127**
Virological Response [Intent To Treat (ITT) - TLOVR, < 50 Copies/ml, Week 48] [units: participants]	**110**	**107**

Statistical Analysis 1 for Virological Response [Intent To Treat (ITT) - TLOVR, < 50 Copies/ml, Week 48]

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Difference in proportion of response [3]	-1.0
95% Confidence Interval	-9.9 to 7.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Assuming a virologic response rate of 90% at 48 weeks for both treatment arms, 111 patients were required per treatment arm to establish non-inferiority of DRV/r versus triple regimen with a maximum allowable difference of 12%, with a one-sided significance level of p=0.025 and 80% power. To account for a maximum of 10% major protocol violations that would be excluded from the on-protocol analysis, 125 patients were recruited in each treatment are, so 250 patients in total.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If at Week 48, the lower limit of the 95% two-sided confidence interval of the difference between DRV/r and DRV/r+2NRTIs exceeds -12%, non-inferiority of the DRV/r 800/100 once a day (O.D) monotherapy versus the DRV/r 800/100 mg O.D. plus two NRTIs triple combination therapy was concluded.
[3]	Other relevant estimation information:
	Difference in proportion of response DRV/r minus DRV/r+2NRTIs.

3. Secondary: Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, < 50 Copies/ml, Week 144] [Time Frame: Week 144]

Measure Type	Secondary
Measure Title	Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, < 50 Copies/ml, Week 144]
Measure Description	Virological response is defined as the number of patients in the PP population with a plasma viral load < 50 HIV RNA copies/ml at Week 144. Treatment failure was defined as two consecutive HIV RNA levels ≥ 50 copies/mL, or discontinuation of randomised treatment (known as TLOVR). In addition, any switch in background nucleoside reverse transcriptase inhibitors (NRTIs) equaled failure* (referred to as a Switch Equals Failure analysis). *Discontinuations and rechallenge with NRTIs are taken into account until Week 144
Time Frame	Week 144
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.
PP population: all randomised subjects who took study drug, and who did not deviate from the protocol.This excludes 13 subjects with major

protocol deviations.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**121**	**122**
Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, < 50 Copies/ml, Week 144] [units: participants]	**94**	**88**

No statistical analysis provided for Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, < 50 Copies/ml, Week 144]

4. Secondary: Virological Response [Intent To Treat (ITT), TLOVR - All Switches Included, < 50 Copies/ml, Week 144] [Time Frame: Week 144]

Measure Type	Secondary
Measure Title	Virological Response [Intent To Treat (ITT), TLOVR - All Switches Included, < 50 Copies/ml, Week 144]
Measure Description	Virological response is defined as the number of patients in the ITT population with a plasma viral load < 50 HIV RNA copies/ml at Week 144. Treatment failure was defined as two consecutive HIV RNA levels ≥ 50 copies/mL, or discontinuation of randomised treatment (known as TLOVR). All switches included means that all data even after any changes of treatment were kept. *Discontinuations and rechallenge with NRTIs are taken into account until start of Week 144 window.
Time Frame	Week 144
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.
ITT population: all randomised patients who took study drug, regardless of their compliance with the protocol.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**129**	**127**
Virological Response [Intent To Treat (ITT), TLOVR - All Switches Included, < 50 Copies/ml, Week 144] [units: participants]	**106**	**106**

Statistical Analysis 1 for Virological Response [Intent To Treat (ITT), TLOVR - All Switches Included, < 50 Copies/ml, Week 144]

Groups [1]	All groups
Difference in proportion of response [2]	1.29
95% Confidence Interval	-7.99 to 10.58

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Difference in proportion of response DRV/r minus DRV/r+2NRTIs.

5. Secondary: Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, <200 Copies/ml, Week 144] [Time Frame: week 144]

Measure Type	Secondary
Measure Title	Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, <200 Copies/ml, Week 144]
Measure Description	Virological response is defined as the number of patients in the PP population with a plasma viral load < 200 HIV RNA copies/ml at Week 144. Treatment failure was defined as two consecutive HIV RNA levels ≥ 50 copies/mL, or discontinuation of randomised treatment (known as TLOVR). In addition, any switch in background nucleoside reverse transcriptase inhibitors (NRTIs) equaled failure* (referred to as a Switch Equals Failure analysis). *Discontinuations and rechallenge with NRTIs are taken into account until Week 144
Time Frame	week 144
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.
PP population: all randomised patients who took study drug, and who did not deviate from the protocol. This excludes 13 patients with major protocol deviations.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	**DRV/r**
Number of Participants Analyzed [units: participants]	**121**	**122**
Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, <200 Copies/ml, Week 144] [units: Participants]	**102**	**95**

No statistical analysis provided for Virological Response [Per Protocol (PP), TLOVR - Switch Equals Failure, <200 Copies/ml, Week 144]

6. Secondary: Mean Change From Baseline in CD4+ Cell Count [Time Frame: at week 4, 12, 24, 36, 48, 60, 72, 84, 96, 112, 128, 144]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CD4+ Cell Count
Measure Description	The mean change in CD4+ cell count from baseline was calculated with a last observation carried forward method; i.e.

	the last observed value was carried forward, irrespective of the reason for discontinuation.
Time Frame	at week 4, 12, 24, 36, 48, 60, 72, 84, 96, 112, 128, 144
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.
ITT: all randomized patients who had at least 1 dose of study medication, regardless of their adherence to the protocol

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	**DRV/r**
Number of Participants Analyzed [units: participants]	**129**	**127**
Mean Change From Baseline in CD4+ Cell Count [units: number of cells/L (x10^6)] Mean (Standard Error)		
week 4	**-16.9 (15.7)**	**-32.9 (14.6)**
week 12	**-23.6 (14.7)**	**-20.7 (15.2)**
week 24	**-5.4 (14.6)**	**-35.8 (14.2)**
week 36	**-1.2 (15.8)**	**-21.1 (14.3)**
week 48	**-19.0 (14.7)**	**-15.1 (16.0)**
week 60	**-4.0 (14.9)**	**-2.3 (14.4)**
week 72	**24.1 (16.1)**	**-12.3 (14.3)**
week 84	**34.6 (17.2)**	**-3.7 (15.0)**
week 96	**49.1 (15.9)**	**54.8 (16.2)**
week 112	**106.0 (16.7)**	**87.5 (16.2)**
week 128	**117.3 (18.3)**	**90.4 (14.9)**
week 144	**99.3 (15.7)**	**94.9 (15.0)**

No statistical analysis provided for Mean Change From Baseline in CD4+ Cell Count

7. Secondary: Resistance Determinations [Time Frame: at each visit from baseline to week 144]

Measure Type	Secondary
Measure Title	Resistance Determinations
Measure Description	Number of patients with resistance mutations at any time point when a patient had a viral load > 50 copies/mL after randomization.
Time Frame	at each visit from baseline to week 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of their adherence to the protocol.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	**DRV/r**
Number of Participants Analyzed [units: participants]	**129**	**127**
Resistance Determinations [units: number of participants]		
>= 1 HIV-1 RNA > 50 copies/mL	**42**	**48**
>= 1 successful genotype after baseline	**23**	**31**
>= 1 IAS-USA primary PI mutations	**1**	**1**
>= 1 DRV RAMs	**0**	**1**
NRTI RAMs	**1**	**0**
M184V mutation	**1**	**0**
no primary PI, DRV, NRTI or M184 V mutations	**22**	**30**

No statistical analysis provided for Resistance Determinations

8. Secondary: Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Total Score [Time Frame: at baseline, week 48, 96 and 144]

Measure Type	Secondary
Measure Title	Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Total Score
Measure Description	The FAHI is a validated health-related quality of life questionnaire. The questionnaire consist of 44 items and includes 5 functional scales (physical, social, emotional, functional and global well-being and cognitive function). Each item is assessing the impact of HIV on a scale from 0 (not at all) to 5 (very much).
Time Frame	at baseline, week 48, 96 and 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of protocol adherence. A LOCF method was used for calculation.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks

DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**126**	**112**
Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Total Score [units: points on a scale] Mean (Standard Error)		
week 48	**1.7 (1.7)**	**1.7 (2.0)**
week 96	**0.4 (1.6)**	**3.5 (2.4)**
week 144	**0.7 (1.7)**	**3.1 (2.4)**

No statistical analysis provided for Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Total Score

9. Secondary: Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Cognitive Function Subscale [Time Frame: at baseline, week 48, 96 and 144]

Measure Type	Secondary
Measure Title	Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Cognitive Function Subscale
Measure Description	The FAHI cognitive function subscale. Each item is assessing the impact of HIV on cognitive function on a scale from 0 (not at all) to 5 (very much).
Time Frame	at baseline, week 48, 96 and 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of protocol adherence. A LOCF method was used for calculation.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**127**	**115**
Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Cognitive Function Subscale [units: points on a scale] Mean (Standard Error)		
week 48	**0.1 (0.2)**	**-0.1 (0.2)**
week 96	**-0.1 (0.2)**	**-0.1 (0.2)**
week 144	**0.1 (0.2)**	**-0.1 (0.2)**

No statistical analysis provided for Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Cognitive Function Subscale

10. Secondary: Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Emotional Well-Being Subscale [Time Frame: at baseline, week 48, 96 and 144]

Measure Type	Secondary
Measure Title	Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Emotional Well-Being Subscale
Measure Description	The FAHI emotional well-being subscale. Each item is assessing the impact of HIV on emotional well-being on a scale from 0 (not at all) to 5 (very much).
Time Frame	at baseline, week 48, 96 and 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of protocol adherence. A LOCF method was used for calculation.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**128**	**118**
Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Emotional Well-Being Subscale [units: points on a scale] Mean (Standard Error)		
week 48	**0.1 (0.6)**	**1.8 (0.7)**
week 96	**1.0 (0.5)**	**1.3 (0.7)**
week 144	**1.4 (0.5)**	**1.7 (0.7)**

No statistical analysis provided for Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Emotional Well-Being Subscale

11. Secondary: Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Functional and Global Well-Being Subscale [Time Frame: at baseline, week 48, 96 and 144]

Measure Type	Secondary
Measure Title	Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Functional and Global Well-Being Subscale
Measure Description	The FAHI functional and global well-being subscale. Each item is assessing the impact of HIV on functional and global well-being on a scale from 0 (not at all) to 5 (very much).
Time Frame	at baseline, week 48, 96 and 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of protocol adherence. A LOCF method was used for calculation.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	**DRV/r**
Number of Participants Analyzed [units: participants]	**127**	**116**
Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Functional and Global Well-Being Subscale [units: points on a scale] Mean (Standard Error)		
week 48	**0.3 (0.8)**	**-0.8 (0.7)**
week 96	**-0.1 (0.7)**	**0.4 (0.9)**
week 144	**-0.6 (0.8)**	**0.0 (1.0)**

No statistical analysis provided for Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Functional and Global Well-Being Subscale

12. Secondary: Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Physical Well-Being Subscale [Time Frame: at baseline, week 48, 96 and 144]

Measure Type	Secondary
Measure Title	Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Physical Well-Being Subscale
Measure Description	The FAHI physical well-being subscale. Each item is assessing the impact of HIV on physical well-being on a scale from 0 (not at all) to 5 (very much).
Time Frame	at baseline, week 48, 96 and 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of protocol adherence. A LOCF method was used for calculation.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks

DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**128**	**118**
Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Physical Well-Being Subscale [units: points on a scale] Mean (Standard Error)		
week 48	**0.6 (0.5)**	**1.0 (0.8)**
week 96	**0.4 (0.5)**	**1.4 (0.9)**
week 144	**0.0 (0.5)**	**1.0 (0.8)**

No statistical analysis provided for Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Physical Well-Being Subscale

13. Secondary: Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Social Well-Being Subscale [Time Frame: at baseline, week 48, 96 and 144]

Measure Type	Secondary
Measure Title	Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Social Well-Being Subscale
Measure Description	The FAHI social well-being subscale. Each item is assessing the impact of HIV on physical well-being on a scale from 0 (not at all) to 5 (very much).
Time Frame	at baseline, week 48, 96 and 144
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.
ITT: all randomised patients who had at least 1 dose of study medication, regardless of protocol adherence. A LOCF method was used for calculation.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks

Measured Values

	DRV/r+2NRTIs	DRV/r
Number of Participants Analyzed [units: participants]	**126**	**115**
Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Social Well-Being Subscale [units: points on a scale] Mean (Standard Error)		
week 48	**0.4 (0.5)**	**-0.2 (0.5)**
week 96	**-0.6 (0.5)**	**0.8 (0.6)**
week 144	**-0.3 (0.5)**	**0.6 (0.6)**

No statistical analysis provided for Change From Baseline in Health-Related Quality of Life - FAHI Questionnaire Social Well-Being Subscale

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study. Mean exposure at the time of primary analysis (Week 48) was 457.3 days for the overall study population (462.3 days for the DRV/r+2NRTIs group and 452.2 days for the DRV/r group).
Additional Description	Adverse events were either reported by the subjects voluntarily or were obtained by means of interviewing subjects in a non-directed manner at study visits.

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks
Total	No text entered.

Serious Adverse Events

	DRV/r+2NRTIs	DRV/r	Total
Total, serious adverse events			
# participants affected / at risk	**14/129 (10.85%)**	**14/127 (11.02%)**	**28/256 (10.94%)**
Blood and lymphatic system disorders			
Anaemia [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Thrombocytopenia [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Cardiac disorders			
Acute Myocardial Infarction [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Eye disorders			
Uveitis [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Gastrointestinal disorders			
Duodenal Ulcer [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Dysphagia [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Vomiting [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
General disorders			
Pyrexia [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**1/127 (0.79%)**	**2/256 (0.78%)**
Hepatobiliary disorders			
Jaundice [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**

Infections and infestations			
Gastroenteritis [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Hepatitis A [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Pneumonia [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Respiratory Tract Infection [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Subcutaneous Abscess [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Bronchitis [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Hepatitis C [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Neurosyphilis [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**2/127 (1.57%)**	**2/256 (0.78%)**
Secondary Syphilis [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Injury, poisoning and procedural complications			
Femoral Neck Fracture [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Incisional Hernia [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Procedural Pain [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Investigations			
Aspartate Aminotransferase Increased [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Csf Pressure Decreased [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Lipase Increased [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Protrusion [*1]			
# participants affected / at risk	**0/129 (0.00%)**	**1/127 (0.79%)**	**1/256 (0.39%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's Disease [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Tongue Neoplasm Malignant Stage Unspecified [*1]			
# participants affected / at risk	**1/129 (0.78%)**	**0/127 (0.00%)**	**1/256 (0.39%)**
Nervous system disorders			
Convulsion [*1]			

# participants affected / at risk	1/129 (0.78%)	0/127 (0.00%)	1/256 (0.39%)
Nervous System Disorder * 1			
# participants affected / at risk	1/129 (0.78%)	0/127 (0.00%)	1/256 (0.39%)
Psychiatric disorders			
Somatoform Disorder * 1			
# participants affected / at risk	1/129 (0.78%)	0/127 (0.00%)	1/256 (0.39%)
Psychotic Disorder * 1			
# participants affected / at risk	0/129 (0.00%)	2/127 (1.57%)	2/256 (0.78%)
Renal and urinary disorders			
Nephrolithiasis * 1			
# participants affected / at risk	1/129 (0.78%)	0/127 (0.00%)	1/256 (0.39%)
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia * 1			
# participants affected / at risk	0/129 (0.00%)	1/127 (0.79%)	1/256 (0.39%)
Respiratory, thoracic and mediastinal disorders			
Asthma * 1			
# participants affected / at risk	0/129 (0.00%)	1/127 (0.79%)	1/256 (0.39%)
Surgical and medical procedures			
Cataract Operation * 1			
# participants affected / at risk	1/129 (0.78%)	0/127 (0.00%)	1/256 (0.39%)
Varicose Vein Operation * 1			
# participants affected / at risk	0/129 (0.00%)	1/127 (0.79%)	1/256 (0.39%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 10.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study. Mean exposure at the time of primary analysis (Week 48) was 457.3 days for the overall study population (462.3 days for the DRV/r+2NRTIs group and 452.2 days for the DRV/r group).
Additional Description	Adverse events were either reported by the subjects voluntarily or were obtained by means of interviewing subjects in a non-directed manner at study visits.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
DRV/r+2NRTIs	800 mg qd (2 x 400 mg tablet) + 2 NRTI for 144 weeks
DRV/r	800 mg qd (2 x 400 mg tablet) monotherapy for 144 weeks
Total	No text entered.

Other Adverse Events

	DRV/r+2NRTIs	DRV/r	Total

Total, other (not including serious) adverse events			
# participants affected / at risk	**98/129 (75.97%)**	**103/127 (81.10%)**	**201/256 (78.52%)**
Gastrointestinal disorders			
Diarrhoea [*1]			
# participants affected / at risk	**26/129 (20.16%)**	**26/127 (20.47%)**	**52/256 (20.31%)**
Vomiting [*1]			
# participants affected / at risk	**9/129 (6.98%)**	**1/127 (0.79%)**	**10/256 (3.91%)**
Nausea [*1]			
# participants affected / at risk	**7/129 (5.43%)**	**5/127 (3.94%)**	**12/256 (4.69%)**
General disorders			
Fatigue [*1]			
# participants affected / at risk	**6/129 (4.65%)**	**7/127 (5.51%)**	**13/256 (5.08%)**
Infections and infestations			
Bronchitis [*1]			
# participants affected / at risk	**12/129 (9.30%)**	**10/127 (7.87%)**	**22/256 (8.59%)**
Nasopharyngitis [*1]			
# participants affected / at risk	**10/129 (7.75%)**	**15/127 (11.81%)**	**25/256 (9.77%)**
Respiratory Tract Infection [*1]			
# participants affected / at risk	**9/129 (6.98%)**	**1/127 (0.79%)**	**10/256 (3.91%)**
Upper Respiratory Tract Infection [*1]			
# participants affected / at risk	**7/129 (5.43%)**	**12/127 (9.45%)**	**19/256 (7.42%)**
Investigations			
Blood Cholesterol Increased [*1]			
# participants affected / at risk	**2/129 (1.55%)**	**7/127 (5.51%)**	**9/256 (3.52%)**
Metabolism and nutrition disorders			
Hypercholesterolaemia [*1]			
# participants affected / at risk	**6/129 (4.65%)**	**19/127 (14.96%)**	**25/256 (9.77%)**
Musculoskeletal and connective tissue disorders			
Back Pain [*1]			
# participants affected / at risk	**4/129 (3.10%)**	**8/127 (6.30%)**	**12/256 (4.69%)**
Nervous system disorders			
Headache [*1]			
# participants affected / at risk	**10/129 (7.75%)**	**12/127 (9.45%)**	**22/256 (8.59%)**
Psychiatric disorders			
Depression [*1]			
# participants affected / at risk	**7/129 (5.43%)**	**12/127 (9.45%)**	**19/256 (7.42%)**
Renal and urinary disorders			
Haematuria [*1]			
# participants affected / at risk	**12/129 (9.30%)**	**7/127 (5.51%)**	**19/256 (7.42%)**
Leukocyturia [*1]			
# participants affected / at risk	**7/129 (5.43%)**	**6/127 (4.72%)**	**13/256 (5.08%)**
Respiratory, thoracic and mediastinal disorders			
Cough [*1]			

# participants affected / at risk	**8/129 (6.20%)**	**7/127 (5.51%)**	**15/256 (5.86%)**
Skin and subcutaneous tissue disorders			
Rash * 1			
# participants affected / at risk	**4/129 (3.10%)**	**8/127 (6.30%)**	**12/256 (4.69%)**
Vascular disorders			
Hypertension * 1			
# participants affected / at risk	**9/129 (6.98%)**	**6/127 (4.72%)**	**15/256 (5.86%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 10.0

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
This study was not blinded and not designed to demonstrate a safety benefit to stopping nucleoside analogues.

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:** Sponsor (SP) shall have the 1st right to present the Data without approval from the Principal Investigator (PI). If no publication is submitted by SP within 12 months after closure, or after SP confirms there will be no publication, the PI shall have the right to publish. Prior to submission, the PI will provide the SP with at least 45 days for review of a manuscript. If requested, the PI will withhold such publication for up to an additional 60 days to allow for filing of a patent application

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

Arribas JR, Horban A, Gerstoft J, Fätkenheuer G, Nelson M, Clumeck N, Pulido F, Hill A, van Delft Y, Stark T, Moecklinghoff C. The MONET trial: darunavir/ritonavir with or without nucleoside analogues, for patients with HIV RNA below 50 copies/ml. AIDS. 2010 Jan 16;24(2):223-30. doi: 10.1097/QAD.0b013e3283348944.

Responsible Party: Janssen-Cilag International NV

ClinicalTrials.gov Identifier:	NCT00458302 History of Changes
Other Study ID Numbers:	**CR013159** TMC114HIV3006 (Other Identifier: Janssen-Cilag International NV) 2006-006437-40 (EudraCT Number)
Study First Received:	April 6, 2007
Results First Received:	February 4, 2010
Last Updated:	December 14, 2012
Health Authority:	Belgium: Ministry of Social Affairs, Public Health and the Environment

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