



Clinical trial results: HIV Post-Exposure Prophylaxis with Darunavir/r (PEPDar) Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2011-001303-13 |
| Trial protocol | DE |
| Global end of trial date | 28 September 2013 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 09 June 2016 |
| First version publication date | 09 June 2016 |

Trial information

Trial identification

| | |
|-----------------------|---------------|
| Sponsor protocol code | TMC114IFD3004 |
|-----------------------|---------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01516970 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Janssen-Cilag G.m.b.H |
| Sponsor organisation address | Jonson & Johnson Platz 1, Neuss, 41470, Germany, |
| Public contact | Clinical Registry Group, Janssen-Cilag G.m.b.H, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Clinical Registry Group, Janssen-Cilag G.m.b.H, ClinicalTrialsEU@its.jnj.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 28 September 2013 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 September 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the rate of early discontinuation from randomized Human Immunodeficiency Virus (HIV) Post exposure Prophylaxis (PEP) for any reason other than confirmation of the negative HIV infection status of the index person in Participants receiving HIV PEP for at least 28 days, and a maximum of 30 days.

Protection of trial subjects:

Safety assessments included the monitoring of adverse events, clinical laboratory tests (Haematology, serum chemistry, and urinalysis), vital sign measurements, electrocardiogram (ECG) recordings, and performing physical examinations.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 25 November 2011 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects**Subjects enrolled per country**

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Germany: 312 |
| Worldwide total number of subjects | 312 |
| EEA total number of subjects | 312 |

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) | 312 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 324 Participants were screened, 305 were assigned to the per-protocol (PP) population, 310 to the Modified Intention-to-Treat (mITT) population and 312 to the Safety population.

Period 1

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

Arms

| | |
|------------------------------|-------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Darunavir/Ritonavir PEP (DRV/r PEP) |

Arm description:

Darunavir (800 mg) in combination with low-dose ritonavir (100 mg) administered once a day for at least 28 days and a maximum of 30 days along with 2 nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs). The NRTIs (including tenofovir/emtricitabine [Truvada], lamivudine/zidovudine [Combivir]) was administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Darunavir |
| Investigational medicinal product code | SUB23573 |
| Other name | DARUNAVIR ETHANOLATE |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Darunavir 800 mg in combination with low-dose ritonavir (100 mg) administered orally once a day for at least 28 days and a maximum of 30 days.

| | |
|--|--------------------|
| Investigational medicinal product name | RITONAVIR |
| Investigational medicinal product code | SUB10342MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Ritonavir 100 mg in combination with darunavir 800 mg administered orally once a day for at least 28 days and a maximum of 30 days along with 2 nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs).

| | |
|--|--------------------|
| Investigational medicinal product name | LAMIVUDINE |
| Investigational medicinal product code | SUB08392MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

The NRTIs (including lamivudine/zidovudine [Combivir]) administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|-------------|
| Investigational medicinal product name | ZIDOVUDINE |
| Investigational medicinal product code | SUB00153MIG |
| Other name | |

| | |
|--------------------------|--------------------|
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

The NRTIs (including lamivudine/zidovudine [Combivir]) administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|------------------|--|
| Arm title | Standard of care Postexposure Prophylaxis (SOCPEP) |
|------------------|--|

Arm description:

Standard of care HIV PEP (as per German-Austrian Guidelines): Administration of the standard of care HIV PEP (postexposure prophylaxis) consisting of 2 NRTIs plus third partner. The NRTIs (tenofovir/emtricitabine [Truvada], lamivudine/zidovudine [Combivir]) and LPV/r (Kaletra) administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | LOPINAVIR |
| Investigational medicinal product code | SUB02970MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Lopinavir administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|--------------------|
| Investigational medicinal product name | RITONAVIR |
| Investigational medicinal product code | SUB10342MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Ritonavir administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|--------------------|
| Investigational medicinal product name | ZIDOVUDINE |
| Investigational medicinal product code | SUB00153MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Zidovudine administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|--------------------|
| Investigational medicinal product name | LAMIVUDINE |
| Investigational medicinal product code | SUB08392MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Lamivudine administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|--------------------|
| Investigational medicinal product name | EFAVIRENZ |
| Investigational medicinal product code | SUB06463MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Efavirenz administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|--------------------|
| Investigational medicinal product name | EMTRICITABINE |
| Investigational medicinal product code | SUB01882MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Emtricitabine administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|--|-------------------------------|
| Investigational medicinal product name | TENOFOVIR DISOPROXIL FUMARATE |
| Investigational medicinal product code | SUB12607MIG |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tenofovir disoproxil fumarate administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| Number of subjects in period 1 | Darunavir/Ritonavir PEP (DRV/r PEP) | Standard of care Postexposure Prophylaxis (SOCPEP) |
|----------------------------------|--|---|
| | | |
| Started | 159 | 153 |
| Completed | 142 | 132 |
| Not completed | 17 | 21 |
| Consent withdrawn by subject | 1 | 1 |
| Other | 8 | 7 |
| Adverse event, serious non-fatal | 1 | 5 |
| Lost to follow-up | 7 | 8 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Darunavir/Ritonavir PEP (DRV/r PEP) |
|-----------------------|-------------------------------------|

Reporting group description:

Darunavir (800 mg) in combination with low-dose ritonavir (100 mg) administered once a day for at least 28 days and a maximum of 30 days along with 2 nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs). The NRTIs (including tenofovir/emtricitabine [Truvada], lamivudine/zidovudine [Combivir]) was administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|-----------------------|--|
| Reporting group title | Standard of care Postexposure Prophylaxis (SOCPEP) |
|-----------------------|--|

Reporting group description:

Standard of care HIV PEP (as per German-Austrian Guidelines): Administration of the standard of care HIV PEP (postexposure prophylaxis) consisting of 2 NRTIs plus third partner. The NRTIs (tenofovir/emtricitabine [Truvada], lamivudine/zidovudine [Combivir]) and LPV/r (Kaletra) administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| Reporting group values | Darunavir/Ritonavir PEP (DRV/r PEP) | Standard of care Postexposure Prophylaxis (SOCPEP) | Total |
|---|-------------------------------------|--|-------|
| Number of subjects | 159 | 153 | 312 |
| Title for AgeCategorical Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 159 | 153 | 312 |
| From 65 to 84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Title for AgeContinuous Units: years | | | |
| arithmetic mean | 34.2 | 32.3 | |
| standard deviation | ± 9.2 | ± 9.33 | - |
| Title for Gender Units: subjects | | | |
| Female | 28 | 28 | 56 |
| Male | 131 | 125 | 256 |

End points

End points reporting groups

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Darunavir/Ritonavir PEP (DRV/r PEP) |
|-----------------------|-------------------------------------|

Reporting group description:

Darunavir (800 mg) in combination with low-dose ritonavir (100 mg) administered once a day for at least 28 days and a maximum of 30 days along with 2 nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs). The NRTIs (including tenofovir/emtricitabine [Truvada], lamivudine/zidovudine [Combivir]) was administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|-----------------------|--|
| Reporting group title | Standard of care Postexposure Prophylaxis (SOCPEP) |
|-----------------------|--|

Reporting group description:

Standard of care HIV PEP (as per German-Austrian Guidelines): Administration of the standard of care HIV PEP (postexposure prophylaxis) consisting of 2 NRTIs plus third partner. The NRTIs (tenofovir/emtricitabine [Truvada], lamivudine/zidovudine [Combivir]) and LPV/r (Kaletra) administered as per the individual Summary of Product Characteristics (SmPCs) at the discretion of either the treating physician or Investigator.

| | |
|----------------------------|------------------------------|
| Subject analysis set title | Per-Protocol (PP) Population |
|----------------------------|------------------------------|

| | |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

The per-protocol population (PP) was defined as all subjects in the mITT (modified intention-to-treat) population and who had received at least 1 dose of study medication.

| | |
|----------------------------|---|
| Subject analysis set title | Modified Intention-to-Treat (mITT) Population |
|----------------------------|---|

| | |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

The mITT population was defined as all subjects who were assigned to receive randomized HIV PEP and were not discontinued due to confirmation of the negative HIV infection status of the index person.

| | |
|----------------------------|----------------------------|
| Subject analysis set title | Safety Analysis Population |
|----------------------------|----------------------------|

| | |
|---------------------------|-----------------|
| Subject analysis set type | Safety analysis |
|---------------------------|-----------------|

Subject analysis set description:

Safety Analysis Set included all participants who received at least one dose of randomized HIV PEP.

Primary: Number of participants with early discontinuation from randomized human immunodeficiency virus postexposure prophylaxis (HIV PEP)

| | |
|-----------------|--|
| End point title | Number of participants with early discontinuation from randomized human immunodeficiency virus postexposure prophylaxis (HIV PEP) ^[1] |
|-----------------|--|

End point description:

Number of participants with early discontinuation from randomized HIV PEP for any reason other than confirmation of the negative HIV infection status of the index person in participants receiving HIV PEP for at least 28 days and a maximum of 30 days.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 30 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive statistics were done, no inferential statistical analyses were performed.

| End point values | Darunavir/Ritonavir PEP (DRV/r PEP) | Standard of care Postexposure Prophylaxis (SOCPEP) | | |
|----------------------------------|-------------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 155 ^[2] | 150 ^[3] | | |
| Units: participants | | | | |
| number (confidence interval 95%) | 10 (3.5 to 11.5) | 15 (6.2 to 15.8) | | |

Notes:

[2] - PP

[3] - PP

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events

| | |
|--|---|
| End point title | Number of Participants With Treatment-Emergent Adverse Events |
| End point description: A treatment-emergent adverse event (TEAE) was defined as an event that occurred in the 14-days treatment period during which it emerged (i.e. started or worsened in severity, relation, or other attribute), and even if the event continued to be present. | |
| End point type | Secondary |
| End point timeframe: Up to Month 3 | |

| End point values | Darunavir/Ritonavir PEP (DRV/r PEP) | Standard of care Postexposure Prophylaxis (SOCPEP) | | |
|-----------------------------|-------------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 159 ^[4] | 153 ^[5] | | |
| Units: participants | | | | |
| number (not applicable) | 131 | 125 | | |

Notes:

[4] - SAS

[5] - SAS

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from baseline in Patient reported outcome questionnaire

| | |
|---|---|
| End point title | Changes from baseline in Patient reported outcome questionnaire |
| End point description: Patient reported outcome (PRO) assessment of functional impairment in conjunction with HIV PEP in 3 inter-related domains (work, social life, and family life), as calculated from subject responses to the Sheehan Disability Scale (SDS) questionnaire. | |
| End point type | Secondary |

End point timeframe:

Up to Month 3

| End point values | Darunavir/Ritonavir PEP (DRV/r PEP) | Standard of care Postexposure Prophylaxis (SOCPEP) | | |
|--------------------------------------|-------------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 159 ^[6] | 153 ^[7] | | |
| Units: unit on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Impairment in work/school/studies | 2.566 (± 2.775) | 3.503 (± 2.891) | | |
| Impairment in social life | 2.465 (± 2.594) | 3.464 (± 2.786) | | |
| Impairment in family life | 2.226 (± 2.624) | 2.954 (± 2.713) | | |
| Overall | 6.987 (± 7.25) | 9.451 (± 7.709) | | |

Notes:

[6] - SAS

[7] - SAS

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|---|--|
| Statistical analysis description: The statistical analysis between the two treatment groups was performed for the factors "Impairment in work/school/studies" with Wilcoxon-Mann-Whitney test. | |
| Comparison groups | Darunavir/Ritonavir PEP (DRV/r PEP) v Standard of care Postexposure Prophylaxis (SOCPEP) |
| Number of subjects included in analysis | 312 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | = 0.0022 |
| Method | Wilcoxon (Mann-Whitney) |

| Statistical analysis title | Statistical analysis 2 |
|---|--|
| Statistical analysis description: The statistical analysis between the two treatment groups was performed for the factors "Impairment in social life" with Wilcoxon-Mann-Whitney test. | |
| Comparison groups | Darunavir/Ritonavir PEP (DRV/r PEP) v Standard of care Postexposure Prophylaxis (SOCPEP) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 312 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | = 0.0008 |
| Method | Wilcoxon (Mann-Whitney) |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

The statistical analysis between the two treatment groups was performed for the factors "Impairment in family life" with Wilcoxon-Mann-Whitney test.

| | |
|---|--|
| Comparison groups | Darunavir/Ritonavir PEP (DRV/r PEP) v Standard of care Postexposure Prophylaxis (SOCPEP) |
| Number of subjects included in analysis | 312 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | = 0.0071 |
| Method | Wilcoxon (Mann-Whitney) |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

The statistical analysis between the two treatment groups was performed for the factors "Overall" with Wilcoxon-Mann-Whitney test.

| | |
|---|--|
| Comparison groups | Darunavir/Ritonavir PEP (DRV/r PEP) v Standard of care Postexposure Prophylaxis (SOCPEP) |
| Number of subjects included in analysis | 312 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | = 0.0017 |
| Method | Wilcoxon (Mann-Whitney) |

Secondary: Percentage of participants who developed detectable HIV antibodies

| | |
|-----------------|--|
| End point title | Percentage of participants who developed detectable HIV antibodies |
|-----------------|--|

End point description:

Seroconversion rate of HIV antibodies while receiving HIV PEP evaluated as the percentage of participants who developed detectable HIV antibodies.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Month 3

| End point values | Darunavir/Ritonavir PEP (DRV/r PEP) | Standard of care Postexposure Prophylaxis (SOCPEP) | | |
|-----------------------------|-------------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 155 ^[8] | 150 ^[9] | | |
| Units: percentage | | | | |
| number (not applicable) | | | | |
| Negative | 99.3 | 100 | | |
| Positive | 0.7 | 0 | | |

Notes:

[8] - PP

[9] - PP

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Month 3

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Standard of care Postexposure Prophylaxis (SOCPEP) |
|-----------------------|--|

Reporting group description:

Comparator standard of care HIV PEP (as per German-Austrian Guidelines): Administration of the standard of care HIV PEP (postexposure prophylaxis) consisting of 2 NRTIs plus third partner.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Darunavir/Ritonavir PEP (DRV/r PEP) |
|-----------------------|-------------------------------------|

Reporting group description:

DRV/r 800/100 mg q.d. with 2 NRTIs: darunavir (800 mg) in combination with low-dose ritonavir (100 mg) administered once a day for at least 28 days and a maximum of 30 days along with 2 nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs).

| Serious adverse events | Standard of care Postexposure Prophylaxis (SOCPEP) | Darunavir/Ritonavir PEP (DRV/r PEP) | |
|--|---|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 153 (0.00%) | 0 / 159 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| Non-serious adverse events | Standard of care Postexposure Prophylaxis (SOCPEP) | Darunavir/Ritonavir PEP (DRV/r PEP) | |
|--|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 111 / 153 (72.55%) | 96 / 159 (60.38%) | |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 153 (1.31%) | 6 / 159 (3.77%) | |
| occurrences (all) | 2 | 6 | |
| Dysgeusia | | | |

| | | | |
|--|-------------------------|-------------------------|--|
| subjects affected / exposed occurrences (all) | 5 / 153 (3.27%) 5 | 1 / 159 (0.63%) 1 | |
| Headache subjects affected / exposed occurrences (all) | 8 / 153 (5.23%) 8 | 19 / 159 (11.95%) 21 | |
| General disorders and administration site conditions | | | |
| Asthenia subjects affected / exposed occurrences (all) | 1 / 153 (0.65%) 1 | 5 / 159 (3.14%) 5 | |
| Fatigue subjects affected / exposed occurrences (all) | 28 / 153 (18.30%) 28 | 21 / 159 (13.21%) 21 | |
| Gastrointestinal disorders | | | |
| Abdominal Pain Upper subjects affected / exposed occurrences (all) | 11 / 153 (7.19%) 13 | 14 / 159 (8.81%) 14 | |
| Diarrhoea subjects affected / exposed occurrences (all) | 76 / 153 (49.67%) 80 | 45 / 159 (28.30%) 46 | |
| Flatulence subjects affected / exposed occurrences (all) | 11 / 153 (7.19%) 11 | 5 / 159 (3.14%) 5 | |
| Nausea subjects affected / exposed occurrences (all) | 41 / 153 (26.80%) 42 | 24 / 159 (15.09%) 26 | |
| Vomiting subjects affected / exposed occurrences (all) | 9 / 153 (5.88%) 9 | 10 / 159 (6.29%) 11 | |
| Skin and subcutaneous tissue disorders | | | |
| Rash subjects affected / exposed occurrences (all) | 4 / 153 (2.61%) 5 | 7 / 159 (4.40%) 7 | |
| Psychiatric disorders | | | |
| Sleep Disorder subjects affected / exposed occurrences (all) | 6 / 153 (3.92%) 6 | 0 / 159 (0.00%) 0 | |

| | | | |
|--|----------------------|----------------------|--|
| Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all) | 4 / 153 (2.61%) 4 | 5 / 159 (3.14%) 5 | |
|--|----------------------|----------------------|--|

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|---|
| 20 October 2011 | The overall reason for the amendment was to include participants with nonoccupational event with documented or potential for HIV exposure. Clarification about duration of treatment and drug accountability was only recorded for DRV/r, inclusion of stratification by exposure type due to the inclusion of subjects with non-occupational exposure, and clarification of statistical analysis in case of premature study termination, deletion of safety evaluations not relevant to the study, and reference to SmPC for Prezista deleted. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported