Clinical trial results:
An open-label randomised two-year trial comparing two first-line regimens in HIV-infected antiretroviral naïve subjects: darunavir/r + tenofovir/emtricitabine vs. darunavir/r + raltegravir

Summary

EudraCT number	2009-015113-44
Trial protocol	ES FR SE IE DK PT AT DE GB PL IT BE NL HU GR
Global end of trial date	14 October 2014

Results information

Result version number	v1 (current)
This version publication date	16 October 2026
First version publication date	16 October 2026

Trial information

Trial identification

Sponsor protocol code	NEAT 001/ANRS 143

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01066962
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Inserm-ANRS
Sponsor organisation address	101 rue de Tolbiac, Paris, France, 75013
Public contact	Pr. Christine Katlama, Hôpital Pitié-Salpêtrière, Service Maladies Infectieuses et Tropicales, +33 1 42 16 01 73,
Scientific contact	Pr. François Raffi, Centre Hospitalier Universitaire de Nantes, Dep. of Infectious Diseases HIV, Clinical Research Unit, +33 2 40 08 33 72, francois.raffi@chu-nantes.fr

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	21 August 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to assess the non-inferiority of darunavir/r + raltegravir compared to darunavir/r + tenofovir/emtricitabine as first-line treatment strategies in HIV-1 infected, antiretroviral naïve adults over at least 96 weeks (i.e. to assess if the absolute difference in the proportion of participants with clinical or virological failure with darunavir/r + raltegravir is at most 9% higher than the proportion of participants with clinical or virological failure with darunavir/r + tenofovir/emtricitabine).

Protection of trial subjects:

This study was conducted in accordance with the updated Declaration of Helsinki, in compliance with the protocol and its amendments approved by competent authorities and ethics committees, and the International Council for Harmonisation guideline for Good Clinical Practice (ICH GCP).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 August 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Ethical reason, Regulatory reason, Scientific research
Long term follow-up duration	39 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Poland: 11
Country: Number of subjects enrolled	Portugal: 24
Country: Number of subjects enrolled	Spain: 78
Country: Number of subjects enrolled	Sweden: 31
Country: Number of subjects enrolled	United Kingdom: 102
Country: Number of subjects enrolled	Austria: 4
Country: Number of subjects enrolled	Belgium: 52
Country: Number of subjects enrolled	Denmark: 25
Country: Number of subjects enrolled	France: 228
Country: Number of subjects enrolled	Germany: 102
Country: Number of subjects enrolled	Greece: 9
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Ireland: 12
Country: Number of subjects enrolled	Italy: 115

Worldwide total number of subjects	805
EEA total number of subjects	703

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)	789
From 65 to 84 years	16
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From August 2010 and September 2011, 940 patients were screened. 805 were randomised in 15 European countries.

Pre-assignment

Screening details:

Main criteria:

Inclusion: patient with confirmed HIV infection, at least 18 years, written informed consent.

Non-inclusion: women without effective contraception method, pregnant or breastfeeding women, women expected to conceive during the study, HIV-2 co-infection.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	RAL+DRV/r

Arm description:

Raltegravir + ritonavir-boosted darunavir arm

Arm type	Experimental
Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	Isentress®, RAL
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Raltegravir 400 mg (Isentress®), 1 tablet twice daily (BID)

Investigational medicinal product name	Darunavir
Investigational medicinal product code	
Other name	Prezista®, DRV
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Darunavir 800 mg, i.e. 2 tablets of 400 mg (Prezista®) once daily (QD)

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

Dosage and administration details:

Ritonavir 100 mg (Norvir®), 1 tablet once daily (QD)

Arm title	TDF-FTC+DRV/r

Arm description:

Tenofovir/emtricitabine + ritonavir-boosted darunavir arm

Arm type	Active comparator

Investigational medicinal product name	Tenofovir/emtricitabine
Investigational medicinal product code	
Other name	Truvada®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tenofovir/emtricitabine 245/200 mg, fixed dose combination (Truvada®), 1 tablet once daily (QD)

Investigational medicinal product name	Darunavir
Investigational medicinal product code	
Other name	Prezista®, DRV
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Darunavir 800 mg, i.e. 2 tablets of 400 mg (Prezista®) once daily (QD)

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

Dosage and administration details:

Ritonavir 100 mg (Norvir®), 1 tablet once daily (QD)

Number of subjects in period 1	RAL+DRV/r	TDF-FTC+DRV/r
Started	401	404
Completed	348	366
Not completed	53	38
Consent withdrawn by subject	14	14
Death	4	1
Lost to follow-up	35	23

Baseline characteristics

Reporting groups	
Reporting group title	RAL+DRV/r
Reporting group description:	
Raltegravir + ritonavir-boosted darunavir arm	
Reporting group title	TDF-FTC+DRV/r
Reporting group description:	
Tenofovir/emtricitabine + ritonavir-boosted darunavir arm	

Reporting group values	RAL+DRV/r	TDF-FTC+DRV/r	Total
Number of subjects	401	404	805
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
median	37	39	
inter-quartile range (Q1-Q3)	31 to 45	31 to 46	-
Gender categorical			
Units: Subjects			
Female	49	46	95
Male	352	358	710

End points

End points reporting groups

Reporting group title	RAL+DRV/r
Reporting group description:	
Raltegravir + ritonavir-boosted darunavir arm	
Reporting group title	TDF-FTC+DRV/r
Reporting group description:	
Tenofovir/emtricitabine + ritonavir-boosted darunavir arm	

Primary: Time to virologic or clinical failure

End point title	Time to virologic or clinical failure
End point description:	
Time to virologic or clinical failure, as the first occurrence of any of the following components: - failure to achieve virologic response by W32 (defined as HIV-1 RNA ≥ 50 copies/mL at W32, confirmed by a subsequent measurement) - change of any component of the initial randomised regimen before W32 because of documented insufficient virologic response, defined as HIV-1 RNA reduction < log10 copies/mL by W18 or HIV-1 RNA ≥ 400 copies/mL at W42 (confirmed by a subsequent measurement) - HIV-1 RNA ≥ 50 copies/mL (confirmed by a subsequent measurement) at any time after W32 - death due to any cause - any new or recurrent AIDS defining event confirmed by the Endpoint Review Committee - any new serious non AIDS defining event confirmed by the Endpoint Review Committee	
End point type	Primary
End point timeframe:	
For the entire duration of the trial.	

End point values	RAL+DRV/r	TDF-FTC+DRV/r		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	401	404		
Units: Participants reaching primary endpoint	77	61		

Statistical analyses

Statistical analysis title	Difference in treatment failure
Comparison groups	RAL+DRV/r v TDF-FTC+DRV/r
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.34

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.88

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Participants reported adverse events during the entire trial.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups	
Reporting group title	TDF-FTC+DRV/r
Reporting group description: Tenofovir/emtricitabine + ritonavir-boosted darunavir arm	
Reporting group title	RAL+DRV/r
Reporting group description: Raltegravir + ritonavir-boosted darunavir arm	

Serious adverse events	TDF-FTC+DRV/r	RAL+DRV/r	
Total subjects affected by serious adverse events			
subjects affected / exposed	59 / 404 (14.60%)	69 / 401 (17.21%)	
number of deaths (all causes)	1	4	
number of deaths resulting from adverse events	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
castleman's disease			
subjects affected / exposed	0 / 404 (0.00%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
diffuse large b-cell lymphoma			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hodgkin's disease			
subjects affected / exposed	1 / 404 (0.25%)	3 / 401 (0.75%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant melanoma			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
testis cancer			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
kaposi's sarcoma			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
plasmablastic lymphoma			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-hodgkin's lymphoma			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
circulatory collapse			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
arterial stenosis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertension			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			

abscess drainage			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast prosthesis implantation			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
suture insertion			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal laminectomy			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hysterectomy			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
surgery			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
hyperthermia			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
multi-organ failure			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	

pyrexia			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
death			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Immune system disorders			
immune reconstitution syndrome			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
metrorrhagia			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical dysplasia			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatitis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine leiomyoma			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
dyspnoea			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung disorder			
subjects affected / exposed	0 / 404 (0.00%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleurisy			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory failure			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
subjects affected / exposed	2 / 404 (0.50%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
completed suicide			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
mania			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
obsessive-compulsive disorder			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
alcohol abuse			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug abuse			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
withdrawal syndrome			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicidal behaviour			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
alanine aminotransferase increased			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aspartate aminotransferase increased			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood creatine phosphokinase increased			
subjects affected / exposed	4 / 404 (0.99%)	9 / 401 (2.24%)	
occurrences causally related to treatment / all	0 / 4	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood triglycerides increased			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 404 (0.99%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Injury, poisoning and procedural complications			
foreign body			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
facial bones fracture			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wrist fracture			
subjects affected / exposed	0 / 404 (0.00%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper limb fracture			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

toxicity to various agents			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon rupture			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sternal fracture			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
concussion			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
wolff-parkinson-white syndrome			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic valve incompetence			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute myocardial infarction			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute coronary syndrome			

subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chest pain			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial ischaemia			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mitral valve incompetence			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
epilepsy			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
grand mal convulsion			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
headache			

subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
speech disorder			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
disorientation			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
confusional state			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dizziness			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
migraine			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
subjects affected / exposed	2 / 404 (0.50%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sciatica			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
anaemia			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
methaemoglobinaemia			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
agranulocytosis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphadenitis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphadenopathy			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
photophobia			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal pain upper			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal fistula			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diarrhoea			

subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis			
subjects affected / exposed	2 / 404 (0.50%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal obstruction			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhoids			
subjects affected / exposed	2 / 404 (0.50%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vomiting			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal fissure			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal disorder			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ileus			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ileus paralytic			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
inguinal hernia			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal prolapse			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
subjects affected / exposed	2 / 404 (0.50%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
salivary gland calculus			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal ulcer			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
biliary colic			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis acute			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatorenal syndrome			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
portal vein thrombosis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin and subcutaneous tissue disorders			
drug rash with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
erythema multiforme			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rash			
subjects affected / exposed	1 / 404 (0.25%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
rash pruritic			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cold sweat			

subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperhidrosis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urticaria			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
renal colic			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal failure acute			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal failure			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anuria			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
goitre			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue			

disorders			
exostosis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
groin pain			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus lesion			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rhabdomyolysis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain in extremity			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
anal abscess			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
amoebic dysentery			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

aids dementia complex			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis			
subjects affected / exposed	0 / 404 (0.00%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
anogenital warts			
subjects affected / exposed	2 / 404 (0.50%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ear infection			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis b			
subjects affected / exposed	0 / 404 (0.00%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
herpes zoster			
subjects affected / exposed	2 / 404 (0.50%)	3 / 401 (0.75%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral discitis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
meningitis viral			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
meningitis			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
penicilliosis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
plasmodium falciparum infection			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumococcal sepsis			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumocystis jiroveci pneumonia			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
subjects affected / exposed	5 / 404 (1.24%)	2 / 401 (0.50%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal abscess			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound infection			

subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
secondary syphilis			
subjects affected / exposed	1 / 404 (0.25%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rhinovirus infection			
subjects affected / exposed	0 / 404 (0.00%)	1 / 401 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchiolitis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacterial prostatitis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cytomegalovirus chorioretinitis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
helicobacter gastritis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis c			
subjects affected / exposed	2 / 404 (0.50%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
herpangina			

subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
herpes virus infection			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower respiratory tract infection			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyonephrosis			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyoderma			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nasopharyngitis			
subjects affected / exposed	2 / 404 (0.50%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung infection			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
viral infection			
subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
hypoglycaemia			

subjects affected / exposed	1 / 404 (0.25%)	0 / 401 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1.24 %

Non-serious adverse events	TDF-FTC+DRV/r	RAL+DRV/r	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	346 / 404 (85.64%)	344 / 401 (85.79%)	
Vascular disorders			
Haemorrhoids			
subjects affected / exposed	10 / 404 (2.48%)	7 / 401 (1.75%)	
occurrences (all)	10	8	
Hypertension			
subjects affected / exposed	10 / 404 (2.48%)	10 / 401 (2.49%)	
occurrences (all)	10	10	
Surgical and medical procedures			
Wart excision			
subjects affected / exposed	6 / 404 (1.49%)	5 / 401 (1.25%)	
occurrences (all)	7	8	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	14 / 404 (3.47%)	15 / 401 (3.74%)	
occurrences (all)	17	16	
Chest pain			
subjects affected / exposed	6 / 404 (1.49%)	5 / 401 (1.25%)	
occurrences (all)	6	5	
Fatigue			
subjects affected / exposed	23 / 404 (5.69%)	21 / 401 (5.24%)	
occurrences (all)	24	25	
Influenza like illness			
subjects affected / exposed	12 / 404 (2.97%)	11 / 401 (2.74%)	
occurrences (all)	13	11	
Oedema peripheral			
subjects affected / exposed	2 / 404 (0.50%)	5 / 401 (1.25%)	
occurrences (all)	2	5	

Pain			
subjects affected / exposed	2 / 404 (0.50%)	5 / 401 (1.25%)	
occurrences (all)	2	5	
Pyrexia			
subjects affected / exposed	21 / 404 (5.20%)	26 / 401 (6.48%)	
occurrences (all)	23	26	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	7 / 404 (1.73%)	5 / 401 (1.25%)	
occurrences (all)	9	5	
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	13 / 404 (3.22%)	8 / 401 (2.00%)	
occurrences (all)	13	8	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	27 / 404 (6.68%)	30 / 401 (7.48%)	
occurrences (all)	31	32	
Oropharyngeal pain			
subjects affected / exposed	12 / 404 (2.97%)	24 / 401 (5.99%)	
occurrences (all)	14	28	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	13 / 404 (3.22%)	10 / 401 (2.49%)	
occurrences (all)	15	11	
Depression			
subjects affected / exposed	20 / 404 (4.95%)	23 / 401 (5.74%)	
occurrences (all)	22	26	
Insomnia			
subjects affected / exposed	19 / 404 (4.70%)	22 / 401 (5.49%)	
occurrences (all)	20	23	
Sleep disorder			
subjects affected / exposed	8 / 404 (1.98%)	19 / 401 (4.74%)	
occurrences (all)	8	21	
Abnormal dreams			

subjects affected / exposed	8 / 404 (1.98%)	3 / 401 (0.75%)	
occurrences (all)	8	3	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	8 / 404 (1.98%)	9 / 401 (2.24%)	
occurrences (all)	9	9	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 404 (0.50%)	7 / 401 (1.75%)	
occurrences (all)	2	7	
Cardiac disorders			
Palpitations			
subjects affected / exposed	2 / 404 (0.50%)	5 / 401 (1.25%)	
occurrences (all)	2	5	
Nervous system disorders			
Dizziness			
subjects affected / exposed	12 / 404 (2.97%)	5 / 401 (1.25%)	
occurrences (all)	13	5	
Headache			
subjects affected / exposed	38 / 404 (9.41%)	38 / 401 (9.48%)	
occurrences (all)	45	39	
Memory impairment			
subjects affected / exposed	5 / 404 (1.24%)	2 / 401 (0.50%)	
occurrences (all)	5	2	
Paraesthesia			
subjects affected / exposed	8 / 404 (1.98%)	8 / 401 (2.00%)	
occurrences (all)	9	9	
Sciatica			
subjects affected / exposed	7 / 404 (1.73%)	9 / 401 (2.24%)	
occurrences (all)	8	9	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 404 (1.49%)	7 / 401 (1.75%)	
occurrences (all)	7	8	
Lymphadenopathy			

subjects affected / exposed	9 / 404 (2.23%)	14 / 401 (3.49%)	
occurrences (all)	10	19	
Leukopenia			
subjects affected / exposed	6 / 404 (1.49%)	0 / 401 (0.00%)	
occurrences (all)	7	0	
Neutropenia			
subjects affected / exposed	6 / 404 (1.49%)	4 / 401 (1.00%)	
occurrences (all)	6	4	
Eye disorders			
Conjunctivitis			
subjects affected / exposed	6 / 404 (1.49%)	9 / 401 (2.24%)	
occurrences (all)	7	9	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	18 / 404 (4.46%)	21 / 401 (5.24%)	
occurrences (all)	21	25	
Abdominal pain upper			
subjects affected / exposed	23 / 404 (5.69%)	20 / 401 (4.99%)	
occurrences (all)	26	22	
Anal fissure			
subjects affected / exposed	5 / 404 (1.24%)	5 / 401 (1.25%)	
occurrences (all)	5	5	
Anogenital dysplasia			
subjects affected / exposed	9 / 404 (2.23%)	2 / 401 (0.50%)	
occurrences (all)	10	2	
Aphthous stomatitis			
subjects affected / exposed	7 / 404 (1.73%)	14 / 401 (3.49%)	
occurrences (all)	8	15	
Constipation			
subjects affected / exposed	4 / 404 (0.99%)	10 / 401 (2.49%)	
occurrences (all)	4	11	
Diarrhoea			
subjects affected / exposed	122 / 404 (30.20%)	99 / 401 (24.69%)	
occurrences (all)	152	132	
Dyspepsia			

subjects affected / exposed	11 / 404 (2.72%)	13 / 401 (3.24%)	
occurrences (all)	12	14	
Flatulence			
subjects affected / exposed	10 / 404 (2.48%)	16 / 401 (3.99%)	
occurrences (all)	10	16	
Gastritis			
subjects affected / exposed	4 / 404 (0.99%)	6 / 401 (1.50%)	
occurrences (all)	4	7	
Nausea			
subjects affected / exposed	27 / 404 (6.68%)	22 / 401 (5.49%)	
occurrences (all)	33	23	
Rectal haemorrhage			
subjects affected / exposed	4 / 404 (0.99%)	5 / 401 (1.25%)	
occurrences (all)	4	6	
Toothache			
subjects affected / exposed	9 / 404 (2.23%)	6 / 401 (1.50%)	
occurrences (all)	10	6	
Vomiting			
subjects affected / exposed	22 / 404 (5.45%)	16 / 401 (3.99%)	
occurrences (all)	25	16	
Abdominal distension			
subjects affected / exposed	6 / 404 (1.49%)	8 / 401 (2.00%)	
occurrences (all)	6	8	
Gastrointestinal disorder			
subjects affected / exposed	3 / 404 (0.74%)	5 / 401 (1.25%)	
occurrences (all)	3	5	
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 404 (1.24%)	3 / 401 (0.75%)	
occurrences (all)	5	4	
Gingivitis			
subjects affected / exposed	6 / 404 (1.49%)	3 / 401 (0.75%)	
occurrences (all)	6	3	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	6 / 404 (1.49%)	5 / 401 (1.25%)	
occurrences (all)	6	5	

Dermatitis			
subjects affected / exposed	9 / 404 (2.23%)	7 / 401 (1.75%)	
occurrences (all)	10	9	
Dry skin			
subjects affected / exposed	7 / 404 (1.73%)	9 / 401 (2.24%)	
occurrences (all)	7	10	
Eczema			
subjects affected / exposed	12 / 404 (2.97%)	18 / 401 (4.49%)	
occurrences (all)	12	21	
Hyperhidrosis			
subjects affected / exposed	1 / 404 (0.25%)	7 / 401 (1.75%)	
occurrences (all)	2	8	
Night sweats			
subjects affected / exposed	4 / 404 (0.99%)	9 / 401 (2.24%)	
occurrences (all)	4	9	
Pruritus			
subjects affected / exposed	11 / 404 (2.72%)	24 / 401 (5.99%)	
occurrences (all)	12	25	
Rash			
subjects affected / exposed	24 / 404 (5.94%)	27 / 401 (6.73%)	
occurrences (all)	26	29	
Seborrhoeic dermatitis			
subjects affected / exposed	9 / 404 (2.23%)	8 / 401 (2.00%)	
occurrences (all)	10	8	
Urticaria			
subjects affected / exposed	0 / 404 (0.00%)	5 / 401 (1.25%)	
occurrences (all)	0	6	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	5 / 404 (1.24%)	6 / 401 (1.50%)	
occurrences (all)	5	8	
Pollakiuria			
subjects affected / exposed	0 / 404 (0.00%)	5 / 401 (1.25%)	
occurrences (all)	0	5	
Proteinuria			

subjects affected / exposed	8 / 404 (1.98%)	4 / 401 (1.00%)	
occurrences (all)	10	4	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	14 / 404 (3.47%)	19 / 401 (4.74%)	
occurrences (all)	16	22	
Back pain			
subjects affected / exposed	20 / 404 (4.95%)	30 / 401 (7.48%)	
occurrences (all)	22	32	
Musculoskeletal pain			
subjects affected / exposed	6 / 404 (1.49%)	6 / 401 (1.50%)	
occurrences (all)	7	6	
Myalgia			
subjects affected / exposed	8 / 404 (1.98%)	16 / 401 (3.99%)	
occurrences (all)	8	16	
Neck pain			
subjects affected / exposed	5 / 404 (1.24%)	6 / 401 (1.50%)	
occurrences (all)	5	6	
Osteopenia			
subjects affected / exposed	2 / 404 (0.50%)	6 / 401 (1.50%)	
occurrences (all)	2	6	
Pain in extremity			
subjects affected / exposed	7 / 404 (1.73%)	11 / 401 (2.74%)	
occurrences (all)	7	12	
Infections and infestations			
Anogenital warts			
subjects affected / exposed	26 / 404 (6.44%)	27 / 401 (6.73%)	
occurrences (all)	32	32	
Bronchitis			
subjects affected / exposed	25 / 404 (6.19%)	34 / 401 (8.48%)	
occurrences (all)	29	45	
Chlamydial infection			
subjects affected / exposed	8 / 404 (1.98%)	6 / 401 (1.50%)	
occurrences (all)	11	6	
Ear infection			

subjects affected / exposed	5 / 404 (1.24%)	3 / 401 (0.75%)	
occurrences (all)	5	5	
Folliculitis			
subjects affected / exposed	15 / 404 (3.71%)	5 / 401 (1.25%)	
occurrences (all)	16	5	
Fungal infection			
subjects affected / exposed	9 / 404 (2.23%)	5 / 401 (1.25%)	
occurrences (all)	9	5	
Fungal skin infection			
subjects affected / exposed	7 / 404 (1.73%)	1 / 401 (0.25%)	
occurrences (all)	8	1	
Gastroenteritis			
subjects affected / exposed	16 / 404 (3.96%)	24 / 401 (5.99%)	
occurrences (all)	18	31	
Genital herpes			
subjects affected / exposed	6 / 404 (1.49%)	11 / 401 (2.74%)	
occurrences (all)	10	14	
Gonorrhoea			
subjects affected / exposed	14 / 404 (3.47%)	13 / 401 (3.24%)	
occurrences (all)	18	20	
Hepatitis C			
subjects affected / exposed	6 / 404 (1.49%)	1 / 401 (0.25%)	
occurrences (all)	6	1	
Herpes simplex			
subjects affected / exposed	6 / 404 (1.49%)	8 / 401 (2.00%)	
occurrences (all)	6	10	
Herpes zoster			
subjects affected / exposed	19 / 404 (4.70%)	19 / 401 (4.74%)	
occurrences (all)	22	24	
Influenza			
subjects affected / exposed	19 / 404 (4.70%)	28 / 401 (6.98%)	
occurrences (all)	21	32	
Lower respiratory tract infection			
subjects affected / exposed	10 / 404 (2.48%)	4 / 401 (1.00%)	
occurrences (all)	13	5	
Nasopharyngitis			

subjects affected / exposed	49 / 404 (12.13%)	61 / 401 (15.21%)	
occurrences (all)	66	80	
Onychomycosis			
subjects affected / exposed	10 / 404 (2.48%)	6 / 401 (1.50%)	
occurrences (all)	10	7	
Oral candidiasis			
subjects affected / exposed	11 / 404 (2.72%)	9 / 401 (2.24%)	
occurrences (all)	14	10	
Oral herpes			
subjects affected / exposed	15 / 404 (3.71%)	6 / 401 (1.50%)	
occurrences (all)	16	6	
Pharyngitis			
subjects affected / exposed	17 / 404 (4.21%)	22 / 401 (5.49%)	
occurrences (all)	19	25	
Pneumonia			
subjects affected / exposed	5 / 404 (1.24%)	6 / 401 (1.50%)	
occurrences (all)	6	6	
Respiratory tract infection			
subjects affected / exposed	9 / 404 (2.23%)	13 / 401 (3.24%)	
occurrences (all)	10	19	
Rhinitis			
subjects affected / exposed	7 / 404 (1.73%)	22 / 401 (5.49%)	
occurrences (all)	8	25	
Secondary syphilis			
subjects affected / exposed	5 / 404 (1.24%)	4 / 401 (1.00%)	
occurrences (all)	6	5	
Sinusitis			
subjects affected / exposed	9 / 404 (2.23%)	7 / 401 (1.75%)	
occurrences (all)	13	7	
Subcutaneous abscess			
subjects affected / exposed	5 / 404 (1.24%)	3 / 401 (0.75%)	
occurrences (all)	5	3	
Syphilis			
subjects affected / exposed	25 / 404 (6.19%)	17 / 401 (4.24%)	
occurrences (all)	26	19	
Tinea versicolour			

subjects affected / exposed	1 / 404 (0.25%)	5 / 401 (1.25%)	
occurrences (all)	1	5	
Tonsillitis			
subjects affected / exposed	5 / 404 (1.24%)	11 / 401 (2.74%)	
occurrences (all)	8	14	
Tooth abscess			
subjects affected / exposed	4 / 404 (0.99%)	5 / 401 (1.25%)	
occurrences (all)	4	5	
Upper respiratory tract infection			
subjects affected / exposed	13 / 404 (3.22%)	14 / 401 (3.49%)	
occurrences (all)	17	17	
Urethritis			
subjects affected / exposed	5 / 404 (1.24%)	10 / 401 (2.49%)	
occurrences (all)	5	10	
Urinary tract infection			
subjects affected / exposed	11 / 404 (2.72%)	7 / 401 (1.75%)	
occurrences (all)	23	8	
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 404 (1.24%)	2 / 401 (0.50%)	
occurrences (all)	5	2	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 404 (0.99%)	5 / 401 (1.25%)	
occurrences (all)	6	6	
Dyslipidaemia			
subjects affected / exposed	5 / 404 (1.24%)	3 / 401 (0.75%)	
occurrences (all)	5	3	
Hypercholesterolaemia			
subjects affected / exposed	5 / 404 (1.24%)	16 / 401 (3.99%)	
occurrences (all)	5	16	
Hyperlipidaemia			
subjects affected / exposed	3 / 404 (0.74%)	5 / 401 (1.25%)	
occurrences (all)	3	5	
Hypertriglyceridaemia			
subjects affected / exposed	4 / 404 (0.99%)	11 / 401 (2.74%)	
occurrences (all)	4	12	

Hypophosphataemia			
subjects affected / exposed	5 / 404 (1.24%)	2 / 401 (0.50%)	
occurrences (all)	5	2	
Vitamin D deficiency			
subjects affected / exposed	22 / 404 (5.45%)	19 / 401 (4.74%)	
occurrences (all)	22	21	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 March 2010	Note: date of new protocol version. The substantial modifications included in the amendments 1 and 2 of the protocol are: - The inclusion criterion relating to contraception in women has been modified; - The ancillary pharmaco-economic study has been modified (only in Italy); - The immunological and virological sub-study has been modified (modification of the number of visits and modification of the volume of blood sampled); - Addition of an exclusion criterion in the bone sub-study.
10 January 2011	Note: date of new protocol version. The substantial modifications included in the amendment 3 of the protocol are: - The inclusion criterion relating to the method for HIV confirmation has been modified; - The method of contraception recommended during the trial was modified; - The inclusion criterion relating to the absence of antiretroviral treatment has been modified; - The inclusion criterion relating to genotypic testing at screening has been modified; - The inclusion criterion relating to CD4 count at screening has been modified; - A criterion for non-inclusion in the neurocognitive sub-study has been removed and two other criteria have been clarified. The list of tests to be performed in this sub-study has been updated; - The list of national coordinating investigators has been updated.
20 March 2012	Note: date of new protocol version. The substantial modifications included in the amendment 4 of the protocol are: - Change of sponsor name; - Modification of the patient information leaflet (information on the conduct of the trial, raltegravir and change of sponsor); - Extension of the inclusion period in the protocol; - Addition of DRESS syndrome to the definition of grade 4 rash; - Modification of the wording of the primary endpoint in the event of virological failure; - Update of the list of national coordinating investigators (3 changes of principal investigators).
17 April 2013	Note: date of new protocol version. The substantial modification included in the amendment 5 of the protocol is the modification of the wording of the primary research objective and the definition of non-inferiority (to take into account a single definition: absolute difference in the proportions of failures in the 2 arms, with a 95% confidence interval).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/25103176