Clinical trial results:
MULTICENTRE STUDY TO ASSESS CHANGES IN BONE MINERAL DENSITY OF THE SWITCH FROM TENOFOVIR TO ABACAVIR IN HIV-1-INFECTED SUBJECTS WITH LOSS OF BONE MINERAL DENSITY.

Summary

EudraCT number	2010-019879-29
Trial protocol	ES
Global end of trial date	06 July 2012

Results information

Result version number	v1 (current)
This version publication date	26 January 2018
First version publication date	26 January 2018

Trial information

Trial identification

Sponsor protocol code	OSTEOTENOFOVIR

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01153217
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Lluita contra la SIDA
Sponsor organisation address	Crta de Canyet s/n, Badalona, Spain, 08916
Public contact	CRA, Fundació Lluita contra la SIDA, +34 93 497 84 14, rescrig@flsida.org
Scientific contact	CRA, Fundació Lluita contra la SIDA, +34 93 497 84 14,

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	06 July 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 July 2012
Global end of trial reached?	Yes
Global end of trial date	06 July 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate changes in BMD after the switch from tenofovir to abacavir in HIV-infected patients with low bone mineral density.

Protection of trial subjects:

not specific

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 July 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 54
Worldwide total number of subjects	54
EEA total number of subjects	54

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)	54
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The inclusion criteria were virological suppression during a tenofovircontaining regimen for more than 48 weeks and meeting the criteria for osteopenia/osteoporosis by DXA scan, according to the WHO classification.

Pre-assignment

Screening details:

Fifty-four patients were enrolled in this clinical trial

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Abacavir group

Arm description:

Abacavir 600mg + Lamivudine 300 mg every 24 hours + 1 PI or 1 NNRTI or raltegravir

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

Dosage and administration details:

Abacavir 600mg + Lamivudine 300mg every 24 hours

Arm title	Tenofovir group

Arm description:

Tenofovir 300 mg + Emtricitabine 200 mg or Lamivudine 300 mg every 24 hours + 1 PI or 1 NNRTI or raltegravir

Arm type	Active comparator
Investigational medicinal product name	Truvada, Atripla, Virad+Emtriva, Virad+Epivir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tenofovir 245mg + Emtricitabine 200mg or Lamivudine 300mg every 24h

Number of subjects in period 1	Abacavir group	Tenofovir group
Started	26	28
Completed	24	25
Not completed	2	3
Adverse event, non-fatal	2	2
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Abacavir group
Reporting group description:	
Abacavir 600mg + Lamivudine 300 mg every 24 hours + 1 PI or 1 NNRTI or raltegravir	
Reporting group title	Tenofovir group
Reporting group description:	
Tenofovir 300 mg + Emtricitabine 200 mg or Lamivudine 300 mg every 24 hours + 1 PI or 1 NNRTI or raltegravir	

Reporting group values	Abacavir group	Tenofovir group	Total
Number of subjects	26	28	54
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	26	28	54
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	48.5	49.1	
standard deviation	± 6.9	± 8.3	-
Gender categorical			
Units: Subjects			
Female	3	6	9
Male	23	22	45

End points

End points reporting groups	
Reporting group title	Abacavir group
Reporting group description:	
Abacavir 600mg + Lamivudine 300 mg every 24 hours + 1 PI or 1 NNRTI or raltegravir	
Reporting group title	Tenofovir group
Reporting group description:	
Tenofovir 300 mg + Emtricitabine 200 mg or Lamivudine 300 mg every 24 hours + 1 PI or 1 NNRTI or raltegravir	

Primary: changes in increase BMD scores: femoral BMD	
End point title	changes in increase BMD scores: femoral BMD
End point description:	
End point type	Primary
End point timeframe:	
from baseline at week 48	

End point values	Abacavir group	Tenofovir group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	28		
Units: percentage (%)				
number (confidence interval 95%)				
from baseline at week 48	2.1 (-0.6 to 4.7)	0.7 (-0.9 to 2.4)		

Statistical analyses

Statistical analysis title	comparing percentage of change between groups
Comparison groups	Abacavir group v Tenofovir group
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.229
Method	t-test, 2-sided

Primary: changes in increase BMD scores: lumbar spine BMD	
End point title	changes in increase BMD scores: lumbar spine BMD

End point description:

End point type	Primary
End point timeframe: from baseline at week 48	

End point values	Abacavir group	Tenofovir group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	28		
Units: percentage (%)				
number (confidence interval 95%)				
from baseline at week 48	-0.7 (-3.8 to 3.3)	-1.2 (-3.8 to 0.4)		

Statistical analyses

Statistical analysis title	comparing percentage of change between groups
Comparison groups	Abacavir group v Tenofovir group
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.312
Method	t-test, 2-sided

Secondary: patients who experienced virological failure and grade 3–4 toxicity

End point title	patients who experienced virological failure and grade 3–4 toxicity
End point description:	

End point type	Secondary
End point timeframe: week 48	

End point values	Abacavir group	Tenofovir group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	28		
Units: percentage (%)				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: from baseline to week 48	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	DAIDS AE GRADING TAB
Dictionary version	1.0
Reporting groups	
Reporting group title	abacavir group
Reporting group description: -	
Reporting group title	tenofovir group
Reporting group description: -	

Serious adverse events	abacavir group	tenofovir group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)	0 / 28 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	abacavir group	tenofovir group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 26 (7.69%)	2 / 28 (7.14%)	
Nervous system disorders			
Anxiety			
subjects affected / exposed	1 / 26 (3.85%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
renal damage			
subjects affected / exposed	0 / 26 (0.00%)	2 / 28 (7.14%)	
occurrences (all)	0	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported