Clinical trial results:
PILOT STUDY TO ASSESS THE SAFETY AND EFICACY OF SWITCHING THE NNRTI OR PI TO MARAVIROC IN HIV-1-INFECTED SUBJECTS WITH PERSISTENT VIREMIA SUPPRESSION EXPERIENCING NNRTI OR PI-RELATED DYSLIPEMIA

Summary

EudraCT number	2009-011868-11
Trial protocol	ES
Global end of trial date	21 May 2012

Results information

Result version number	v1 (current)
This version publication date	26 January 2020
First version publication date	26 January 2020

Trial information

Trial identification

Sponsor protocol code	MARAVI-SWITCH

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00966329
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	Fundació Lluita contra la SIDA, Fundació Lluita contra la SIDA, 34 93 497 84 14, sgel@flsida.org
Scientific contact	Fundació Lluita contra la SIDA, 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	21 May 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 May 2012
Global end of trial reached?	Yes
Global end of trial date	21 May 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the rates of virological suppression <50 copies/mL in subjects switching to MRV or remaining on their previous ARV regimen.

Protection of trial subjects:

not specific

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 October 2009
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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

30 subjects with R5 HIV-1 were randomized 1:1 to switch the non-nucleoside reverse transcriptase inhibitor or ritonavir-boosted protease inhibitor to maraviroc or to continue the same antiretroviral treatment

Pre-assignment

Screening details:

Eighty HIV-1-infected aviraemic adults on stable antiretroviral treatment for ≥1 year and no antiretroviral drug resistance were screened for the presence of non-R5 HIV by triplicate proviral V3 population sequencing. 37 had non-R5 viruses and 13 did not fulfil the inclusion criteria.

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	Control group

Arm description:

to continue with the same HAART

Arm type	non-active comparator
Investigational medicinal product name	Atazanavir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

300 mg QD

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

Dosage and administration details:

100 mg

Investigational medicinal product name	lopinavir/ritonavir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

250mg

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

Dosage and administration details: 700mg	
Investigational medicinal product name	efavirenz
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 600mg	
Investigational medicinal product name	nevirapine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Ocular use
Dosage and administration details: 400mg	
Arm title	Experimental group
Arm description: to switch from the NNRTI/PI to maraviroc during 48 weeks.	
Arm type	Experimental
Investigational medicinal product name	Maraviroc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 300 mg BiD	

Number of subjects in period 1	Control group	Experimental group
Started	15	15
Completed	14	14
Not completed	1	1
Adverse event, non-fatal	-	1
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Control group
Reporting group description: to continue with the same HAART	
Reporting group title	Experimental group
Reporting group description: to switch from the NNRTI/PI to maraviroc during 48 weeks.	

Reporting group values	Control group	Experimental group	Total
Number of subjects	15	15	30
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)	15	15	30
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
median	39	42	
inter-quartile range (Q1-Q3)	37 to 49	37 to 47	-
Gender categorical Units: Subjects			
Female	1	1	2
Male	14	14	28

End points

End points reporting groups	
Reporting group title	Control group
Reporting group description: to continue with the same HAART	
Reporting group title	Experimental group
Reporting group description: to switch from the NNRTI/PI to maraviroc during 48 weeks.	

Primary: HIV-1 RNA <50 copies/mL	
End point title	HIV-1 RNA <50 copies/mL
End point description:	
End point type	Primary
End point timeframe: week 48	

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: subjects	15	14		

Statistical analyses

Statistical analysis title	Comparing proportions
Statistical analysis description: comparing proportions between groups Week 48	
Comparison groups	Control group v Experimental group
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	> 0.05
Method	Chi-squared

Secondary: Total Cholesterol	
End point title	Total Cholesterol
End point description:	
End point type	Secondary

End point timeframe:
from baseline to week 48

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))				
baseline	4.8 (3.8 to 5.6)	5 (4.8 to 5.2)		
week 48	5.4 (4 to 5.7)	4.3 (4.1 to 4.72)		

Statistical analyses

No statistical analyses for this end point

Secondary: HDL cholesterol

End point title	HDL cholesterol

End point description:

End point type	Secondary

End point timeframe:
from baseline to week 48

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))				
baseline	1.22 (0.96 to 1.58)	1.3 (1.15 to 1.52)		
week 48	1.22 (0.96 to 1.58)	1.25 (1.08 to 1.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: LDL cholesterol

End point title	LDL cholesterol

End point description:

End point type	Secondary

End point timeframe:
from baseline to week 48

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: mmol/L				
median (inter-quartile range (Q1-Q3))				
baseline	3.11 (1.93 to 3.43)	2.9 (2.7 to 3.2)		
week 48	2.92 (2.28 to 3.46)	2.5 (2.37 to 2.66)		

Statistical analyses

No statistical analyses for this end point

Secondary: CD4+ T cells

End point title	CD4+ T cells

End point description:

End point type	Secondary

End point timeframe:
from baseline to wk48

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: cells/mm3				
median (inter-quartile range (Q1-Q3))				
baseline	791 (542 to 996)	639 (430 to 770)		
wk48	699 (489.5 to 1128.5)	738.5 (567.75 to 926.75)		

Statistical analyses

Statistical analysis title	Comparing between groups
Statistical analysis description: Week 48	
Comparison groups	Control group v Experimental group
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.085
Method	Wilcoxon (Mann-Whitney)

Secondary: Triglycerides

End point title	Triglycerides
End point description:	

End point type	Secondary
End point timeframe: from baseline to wk48	

End point values	Control group	Experimental group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: mmol/l				
median (inter-quartile range (Q1-Q3))				
baseline	1.7 (0.9 to 2.5)	1.2 (0.8 to 1.7)		
wk48	1.6 (1.4 to 3.1)	1 (0.67 to 1.22)		

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	Experimental group

Reporting group description: -

Serious adverse events	Experimental group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Experimental group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 May 2009	Primary endpoint modified
25 November 2009	1. new study title 2. lipid profile as secondary endpoint 3. exclusion criteria deleted 4. study medcation provided by the sponsor
16 February 2010	principal investigator switch

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported