Clinical trial results:
ESTUDIO PILOTO PARA COMPARAR LOS PARÁMETROS FARMACOCINÉTICOS EN PLASMA E INTRACELULARES DE RALTEGRAVIR ADMINISTRADO UNA VEZ AL DÍA EN PACIENTES ADULTOS INFECTADOS POR EL VIH (Plasma and Intracellular (Peripheral Blood Mononuclear Cells) Pharmacokinetics of Once-Daily Raltegravir (800 Milligrams) in HIV-Infected Patients)

Summary

EudraCT number	2009-014313-27
Trial protocol	ES
Global end of trial date	15 December 2009

Results information

Result version number	v1 (current)
This version publication date	05 January 2018
First version publication date	05 January 2018

Trial information

Trial identification

Sponsor protocol code	RAL-IC

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00995241
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, jtoro@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	15 December 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 December 2009
Global end of trial reached?	Yes
Global end of trial date	15 December 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study was to evaluate the plasma and intracellular pharmacokinetics of raltegravir in HIV-infected patients receiving once-daily raltegravir.

Protection of trial subjects:

not specific

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 November 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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	5
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients whose HIV-1 RNA load was <50 copies/ml and who were receiving antiretroviral monotherapy with lopinavir-ritonavir at 400/100 mg
twice-daily for at least 4 weeks prior to their inclusion were enrolled.

Pre-assignment

Screening details:

Five HIV-infected patients were enrolled

Period 1

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

Arms

Arm title	Experimental group

Arm description:

Lopinavir-ritonavir plus raltegravir

Arm type	Experimental
Investigational medicinal product name	lopinavir/ritonavir (LPV/r)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

400/100 mg twice-daily

Investigational medicinal product name	raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

800 mg once daily from days 0 to 10

Number of subjects in period 1	Experimental group
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	overall

Reporting group description: -

Reporting group values	overall	Total	
Number of subjects	5	5	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	5	5	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	40		
inter-quartile range (Q1-Q3)	24 to 47	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	5	5	

End points

End points reporting groups

Reporting group title	Experimental group
Reporting group description: Lopinavir-ritonavir plus raltegravir	

Primary: Pharmacokinetic parameters for raltegravir: maximum concentrations

End point title	Pharmacokinetic parameters for raltegravir: maximum concentrations[1]
End point description:	
End point type	Primary
End point timeframe: day 10	

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: one single arm study

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: ng/ml				
geometric mean (full range (min-max))				
plasma	2640 (887 to 10605)			
PBMCs	199 (82 to 857)			

Statistical analyses

No statistical analyses for this end point

Primary: Pharmacokinetic parameters for raltegravir: concentrations at the end of the dosing interval

End point title	Pharmacokinetic parameters for raltegravir: concentrations at the end of the dosing interval[2]
End point description:	
End point type	Primary
End point timeframe: day 10	

Notes:

[2] - 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: one single arm study

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: ng/ml				
geometric mean (full range (min-max))				
plasma	89 (51 to 200)			
PBMCs	7 (2 to 15)			

Statistical analyses

No statistical analyses for this end point

Primary: pharmacokinetic parameters for raltegravir: the geometric mean

End point title	pharmacokinetic parameters for raltegravir: the geometric mean[3]

End point description:

End point type	Primary

End point timeframe:

day 10

Notes:

[3] - 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: one single arm study

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: ng*h/ml				
geometric mean (full range (min-max))				
plasma	12200 (5152 to 30130)			
PBMCs	909 (499 to 2189)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from baseline to week 4	
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 / 5 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	experimental group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: no adverse events (neither non-serious nor serious adverse events) occured in this clinical trial

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 November 2009	Changes in the supply, packaging, labeling and storage of the investigational product

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported