Clinical trial results:
Removal of dolutegravir by hemodialysis in HIV-infected patients with end-stage renal disease.

Summary

EudraCT number	2015-000856-16
Trial protocol	ES
Global end of trial date	03 July 2015

Results information

Result version number	v1 (current)
This version publication date	11 August 2017
First version publication date	11 August 2017

Trial information

Trial identification

Sponsor protocol code	DTG_HD

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02487706
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	Unitat VIH, Fundació Lluita contra la SIDA, +34 93497 84 14, rescrig@flsida.org
Scientific contact	Unitat VIH, Fundació Lluita contra la SIDA, +34 93497 84 14, rescrig@flsida.org

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	03 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 July 2015
Global end of trial reached?	Yes
Global end of trial date	03 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate hemodialysis extraction ratio and clearance of dolutegravir in HIV-infected patients with end-stage renal disease.

Protection of trial subjects:

not specific

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 June 2015
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: -

Pre-assignment

Screening details:

Five anuric 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	Experimenal arm

Arm description:

dolutegravir 50 mg once daily was added to their stable cART for five days.

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

Dosage and administration details:

50mg/day

Number of subjects in period 1	Experimenal arm
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	53		
inter-quartile range (Q1-Q3)	41.3 to 69.5	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	4	4	

End points

End points reporting groups

Reporting group title	Experimenal arm
Reporting group description: dolutegravir 50 mg once daily was added to their stable cART for five days.	

Primary: Dolutegravir concentrations in plasma: concentration in plasma at the end of the dialysis session

End point title	Dolutegravir concentrations in plasma: concentration in plasma at the end of the dialysis session[1]
End point description:	
End point type	Primary
End point timeframe: day 5	

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 analysis of 5 patients. No comparisons were made

End point values	Experimenal arm			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: mg/l				
median (full range (min-max))	1.89 (0.86 to 2.77)			

Statistical analyses

No statistical analyses for this end point

Primary: hemodialysis extraction ratio

End point title	hemodialysis extraction ratio[2]
End point description:	
End point type	Primary
End point timeframe: day 5	

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: Descriptive analysis of 5 patients. No comparisons were made

End point values	Experimenal arm			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: percentage (%)				
median (inter-quartile range (Q1-Q3))	7 (1 to 25)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from baseline to day 5	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	DAIDS AE GRADING TAB
Dictionary version	2.0

Reporting groups	
Reporting group title	experimental arm

Reporting group description: -

Serious adverse events	experimental arm		
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: 1 %

Non-serious adverse events	experimental arm		
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: There were neither non-serious adverse events nor adverse events in this clinical trial.

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