



## 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
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02487706
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Fundació Lluïta contra la SIDA
Sponsor organisation address	Crta de Canyet s/n, Badalona, Spain, 08916
Public contact	Unitat VIH, Fundació Lluïta contra la SIDA, +34 93497 84 14, rescrig@flsida.org
Scientific contact	Unitat VIH, Fundació Lluïta 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:

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**Results analysis stage**

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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:

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**General information about the trial**

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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:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Spain: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

Notes:

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**Subjects enrolled per age group**

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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

<b>Arm title</b>	Experimenal arm
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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

<b>Number of subjects in period 1</b>	Experimenal arm
Started	5
Completed	5

## Baseline characteristics

### Reporting groups

Reporting group title	overall
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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	Experimental 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 <sup>[1]</sup>
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End point description:

End point type	Primary
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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

<b>End point values</b>	Experimental 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 <sup>[2]</sup>
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End point description:

End point type	Primary
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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

<b>End point values</b>	Experimental 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

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No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

from baseline to day 5

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	DAIDS AE GRADING TAB
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Dictionary version	2.0
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### Reporting groups

Reporting group title	experimental arm
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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

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported