



Clinical trial results: Removal of Doravirine by Hemodialysis in HIV-Infected Patients with End-Stage Renal Disease

Summary

EudraCT number	2020-004454-30
Trial protocol	ES
Global end of trial date	14 June 2021

Results information

Result version number	v1 (current)
This version publication date	08 July 2022
First version publication date	08 July 2022

Trial information

Trial identification

Sponsor protocol code	DORA-HD
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04689737
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació de Lluita contra la SIDA, les Malalties Infeccioses i la Promoció de la Salut i La Ciència
Sponsor organisation address	S/N Carretera de Canyet, Badalona, Spain, 08916
Public contact	FLS-Research Support, Fundació de Lluita contra la SIDA, les Malalties Infeccioses i la Promoció de la Salut i La Ciència, +34 934657897, jmolto@lluaita.org
Scientific contact	FLS-Research Support, Fundació de Lluita contra la SIDA, les Malalties Infeccioses i la Promoció de la Salut i La Ciència, +34 934657897, jmolto@lluaita.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	14 June 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the hemodialysis extraction ratio of doravirine in HIV-infected patients with ESRD undergoing intermittent hemodialysis.

Protection of trial subjects:

not specified

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2021
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: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	7
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was done at three major HIV clinics in Catalonia, Spain, in 2021:

- Hospital Germans Trias i Pujol, Badalona, Spain
- Hospital U. de Bellvitge, Hospitalet de Llobregat, Spain
- Hospital U. Vall d'Hebron, Barcelona, Spain

Pre-assignment

Screening details:

Eight participants with HIV infection and ESRD undergoing routine hemodialysis: Males and females* aging ≥ 18 years with Stable antiretroviral treatment for at least 2 weeks before to enrolment and with optimal adherence to antiretroviral treatment (defined as less than 2 missed doses within the previous week)

Period 1

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

Arms

Arm title	Arm 1
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Arm description:

Single arm

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

Dosage and administration details:

100mg

Number of subjects in period 1	Arm 1
Started	8
Completed	8

Baseline characteristics

Reporting groups

Reporting group title	Overall period
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Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	8	8	
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)	7	7	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	2	2	
Male	6	6	

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description:	
Single arm	

Primary: Doravirine hemodialysis extraction ratio

End point title	Doravirine hemodialysis extraction ratio ^[1]
End point description:	
% doravirine in blood samples entering ('Cin') and leaving ('Cout') the dialyzer collected during the dialysis session	
End point type	Primary
End point timeframe:	
day 6	
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: No formal statistical comparisons are envisioned.	

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: noon unit				
median (full range (min-max))	34.3 (25.8 to 41.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doravirine Concentration in plasma at the end of dialysis session

End point title	Doravirine Concentration in plasma at the end of dialysis session
End point description:	
ng/mL	
End point type	Secondary
End point timeframe:	
day 6	

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: noon unit				
median (full range (min-max))	785 (101 to 1851)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of doravirine in plasma

End point title	Ratio of doravirine in plasma
End point description: Ratio of doravirine concentration in plasma after/before the haemodialysis session	
End point type	Secondary
End point timeframe: day 6	

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: noon unit				
median (full range (min-max))	0.8 (0.6 to 1.0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 to Day 6

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	single arm
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Reporting group description: -

Serious adverse events	single arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Cardiac disorder	Additional description: Cardiac insufficiency		
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hyperkalaemia			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	single arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)		
General disorders and administration site conditions			
Headache			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences (all)	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