Clinical trial results:
Tenofovir DP concentrations in seminal cells and semen quality in HIV-1 infected patients receiving a TAF containing regimen

Summary

EudraCT number	2016-001371-69
Trial protocol	ES
Global end of trial date	19 October 2017

Results information

Result version number	v1 (current)
This version publication date	21 December 2023
First version publication date	21 December 2023

Trial information

Trial identification

Sponsor protocol code	EVITAs

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fundación FLS de Lucha Contra el Sida, las Enfermedades Infecciosas y la Promoción de la Salud y la Ciencia
Sponsor organisation address	Ctra. de Canyet s/n, Badalona, Spain, 08916
Public contact	Antonio Navarro, Fundación FLS de Lucha Contra el Sida, las Enfermedades Infecciosas y la Promoción de la Salud y la, +34 675335888, anavarro@irsicaixa.es
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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	16 August 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate intracellular concentrations of tenofovir diphosphate (TFV-DP) in seminal mononuclear (SMC) cells of HIV-1 infected men receiving ART with TAF/FTC/EVG/COBI.

Protection of trial subjects:

Although assessed treatment is approved and is used in routine care, the sponsor contracted an insurance as a mandatory aspect defined in the legal framework of the country site due a different procedures performed during the clinical trial out of routine clinical practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 July 2016
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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects who met inclusion criteria and accepted to sign the informed consent to participate will be cited for a screening visit. A total of 15 HIV-infected patients were selected at the screening phase.

Pre-assignment

Screening details:

15 patients were screened

Pre-assignment period milestones

Number of subjects started	15
Number of subjects completed	15

Period 1

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

Arms

Arm title	EVG/c/FTC/TAF

Arm description:

Elvitgeravir boosted with cobicistat and Tenofovir alafenamide (TAF) and emtricitabine (FTC) co-formulated as single tablet and administered orally once daily

Arm type	Experimental
Investigational medicinal product name	Elvitegravir, cobicistat, Emtricitabine and tenofovir alafenamide fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

elvitegravir 150 mg, cobicistat 150 mg, Emtricitabine 200 mg, tenofovir alafenamide fumarate 10 mg once daily.

Number of subjects in period 1	EVG/c/FTC/TAF
Started	15
Completed	14
Not completed	1
Lost to follow-up	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	EVG/c/FTC/TAF

Reporting group description:

Elvitgeravir boosted with cobicistat and Tenofovir alafenamide (TAF) and emtricitabine (FTC) co-formulated as single tablet and administered orally once daily

Primary: Tenofovir alafenamide fumarate concentration in seminal plasma

End point title	Tenofovir alafenamide fumarate concentration in seminal plasma[1]

End point description:

End point type	Primary

End point timeframe:

12 weeks

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: Data reported has been a descriptive analysis

End point values	EVG/c/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ng/ml				
median (inter-quartile range (Q1-Q3))	110 (73 to 336)			

Statistical analyses

No statistical analyses for this end point

Primary: Tenofovir alafenamide fumarate concentration in blood plasma

End point title	Tenofovir alafenamide fumarate concentration in blood

End point description:

End point type	Primary

End point timeframe:

12 weeks

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: Data reported has been a descriptive analysis

End point values	EVG/c/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ng/ml				
median (inter-quartile range (Q1-Q3))	9.17 (4.6 to 14.9)			

Statistical analyses

No statistical analyses for this end point

Primary: tenofovir diphosphate (tenofovir alafenamide fumarate) concentration in peripheral blood mononuclear cells

End point title	tenofovir diphosphate (tenofovir alafenamide fumarate) concentration in peripheral blood mononuclear cells[3]

End point description:

End point type	Primary

End point timeframe:

12 weeks

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: Data reported has been a descriptive analysis

End point values	EVG/c/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: fmol/106 cells				
median (inter-quartile range (Q1-Q3))	637.29 (213.65 to 1154.36)			

Statistical analyses

No statistical analyses for this end point

Primary: tenofovir diphosphate (tenofovir alafenamide fumarate) concentration in seminal mononuclear cells

End point title	tenofovir diphosphate (tenofovir alafenamide fumarate) concentration in seminal mononuclear cells[4]

End point description:

End point type	Primary

End point timeframe:

12 weeks

Notes:

[4] - 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: Data reported has been a descriptive analysis

End point values	EVG/c/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: fmol/106 cells				
median (inter-quartile range (Q1-Q3))	27.55 (10.4 to 468.88)			

Statistical analyses

No statistical analyses for this end point

Primary: Tenofovir alafenamide fumarate seminal plasma/blood plasma concentration ratio

End point title	Tenofovir alafenamide fumarate seminal plasma/blood plasma concentration ratio[5]

End point description:

End point type	Primary

End point timeframe:

12 week

Notes:

[5] - 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: Data reported has been a descriptive analysis

End point values	EVG/c/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ratio				
median (inter-quartile range (Q1-Q3))	11.96 (7.92 to 51.16)			

Statistical analyses

No statistical analyses for this end point

Primary: tenofovir diphosphate seminal mononuclear cells/ peripheral blood mononuclear cells concentration ratio

End point title	tenofovir diphosphate seminal mononuclear cells/ peripheral blood mononuclear cells concentration ratio[6]

End point description:

End point type	Primary

End point timeframe:

12 weeks

Notes:

[6] - 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: Data reported has been a descriptive analysis

End point values	EVG/c/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ratio				
median (inter-quartile range (Q1-Q3))	0.06 (0.01 to 0.41)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 14 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1

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

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: Non-serious adverse event were reported during the 16 weeks of follow up

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