



## Clinical trial results:

### Evaluation of (doravirine / lamivudine / tenofovir disoproxil fumarate) (Delstrigo®) as a New Strategy for non-occupational Post Exposure Prophylaxis, a Prospective Open Label Study (DORAVIPEP).

#### Summary

EudraCT number	2019-004140-30
Trial protocol	ES
Global end of trial date	28 July 2022

#### Results information

Result version number	v1 (current)
This version publication date	27 August 2025
First version publication date	27 August 2025

#### Trial information

##### Trial identification

Sponsor protocol code	DORAVIPEP
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04233372
WHO universal trial number (UTN)	-

Notes:

##### Sponsors

Sponsor organisation name	Fundació Clinic per a la Recerca Biomèdica
Sponsor organisation address	C/ ROSSELLO, 149 - 153, Barcelona, Spain,
Public contact	Joan Albert Arnaiz, CTU CLINIC, 34 932279838, jaarnaiz@clinic.cat
Scientific contact	Joan Albert Arnaiz, CTU CLINIC, 34 932279838, jaarnaiz@clinic.cat

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	28 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 July 2022
Global end of trial reached?	Yes
Global end of trial date	28 July 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To estimate the proportion of subjects who correctly complete (for 28 days) the entire antiretroviral treatment proposed in the study.

Protection of trial subjects:

Participants provided written informed consent in accordance with the Declaration of Helsinki. Personal data were anonymized and handled under strict confidentiality protocols. Clinical follow-up was conducted at multiple time points to monitor safety, including laboratory tests and adverse event assessments. Adherence to treatment was evaluated using the validated SMAQ questionnaire

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2020
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: 399
Worldwide total number of subjects	399
EEA total number of subjects	399

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)	399
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

1535 subjects received PEP prescriptions between September 2020 and February 2022

### Pre-assignment

Screening details:

406 subjects Screened subjects: met PEP criteria and were visited in the emergency department of Hospital Clínic of Barcelona. 1 subject was a screening failure.

405 subjects Entered the study: 6 subjects were excluded after the initial evaluation because they didn't meet the selection criteria (n=1) and/or had multiple entries (n=5).

### 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	DOR/3TC/TDF
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Arm description:

Single-arm with single-tablet regimen of doravirine/lamivudine/tenofovir disoproxil fumarate for 28 days.

Arm type	Experimental
Investigational medicinal product name	Doravirine / lamivudine / tenofovir disoproxil fumarate
Investigational medicinal product code	
Other name	Delstrigo®
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg doravirine, 300 mg lamivudine, 300 mg tenofovir disoproxil fumarate equivalent to 245 mg de tenofovir disoproxil.

1 coated tablet for day.

Treatment will be administered 28 days maximum

Number of subjects in period 1	DOR/3TC/TDF
Started	399
Completed	285
Not completed	114
Consent withdrawn by subject	2
Adverse event, non-fatal	8
Lost to follow-up	104

## Baseline characteristics

### Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	399	399	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
median	30		
inter-quartile range (Q1-Q3)	27 to 36	-	
Gender categorical			
Units: Subjects			
Female	32	32	
Male	364	364	
Non binary	3	3	
Race/Ethnicity			
Units: Subjects			
Europe	231	231	
Latin America	135	135	
Asia	7	7	
Africa	7	7	
North America	2	2	
Unknown	17	17	

## End points

### End points reporting groups

Reporting group title	DOR/3TC/TDF
Reporting group description: Single-arm with single-tablet regimen of doravirine/lamivudine/tenofovir disoproxil fumarate for 28 days.	

### Primary: Proportion of Participants Who Did Not Complete the 28-day PEP Regimen

End point title	Proportion of Participants Who Did Not Complete the 28-day PEP Regimen <sup>[1]</sup>
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End point description:

PEP noncompletion is considered in cases:

1. If the subject dies.
2. Does not go to visits (loss of follow-up)
3. Change or suspend the treatment under study for any
4. Consent withdrawal

End point type	Primary
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End point timeframe:

28 days

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: The primary endpoint (proportion of participants who did not complete the 28-day PEP regimen) was analyzed using descriptive statistics. Absolute frequencies and percentages were reported, along with 95% confidence intervals. The analysis was performed on the intention-to-treat (ITT) population. This approach is appropriate given the nature of the endpoint and the single-arm design of the study.

End point values	DOR/3TC/TDF			
Subject group type	Reporting group			
Number of subjects analysed	399			
Units: Percentage (%)				
arithmetic mean (confidence interval 95%)	29 (24 to 33)			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

9Adverse event data were collected from Day 0 (start of treatment) through Week 12 (approximately 84 days).

Adverse event reporting additional description:

AEs were assessed via clinical interview, lab tests, and documented in the CRF using MedDRA. Severity (WHO grading), causality, and outcome were recorded. SAEs and treatment-related AEs were tracked. Monitoring included spontaneous reporting and structured follow-up.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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### Reporting groups

Reporting group title	DOR/3TC/TDF
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Reporting group description:

ITT population. All participants who received at least one dose of DOR/3TC/TDF (Delstrigo®) for nonoccupational HIV-1 postexposure prophylaxis.

Serious adverse events	DOR/3TC/TDF		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 399 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	DOR/3TC/TDF		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	123 / 399 (30.83%)		
Nervous system disorders			
Neurological			
subjects affected / exposed	37 / 399 (9.27%)		
occurrences (all)	37		
Gastrointestinal disorders			
Diarrhea, Abdominal pain			
subjects affected / exposed	63 / 399 (15.79%)		
occurrences (all)	63		
Infections and infestations			

Infections			
subjects affected / exposed	28 / 399 (7.02%)		
occurrences (all)	28		

## 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Open-label, single-arm design limits causal inference. PrEP rollout may have reduced seroconversion rates. COVID-19 impacted follow-up and AE reporting. MSM-focused sample limits generalizability. Adherence self-reported.
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/37539061>