

**Clinical trial results:****COMPARISON OF TWO ANTIRETROVIRAL ALTERNATIVE COMBINATIONS IN HIV-1 POST-EXPOSURE PROPHYLAXIS: TENOFOVIR+EMTRICITABINE (TRUVADA®) + LOPINAVIR/RITONAVIR (KALETRA®) VS TENOFOVIR+EMTRICITABINE+ COBICISTAT + ELVITEGRAVIR (STRIBILD®). A PROSPECTIVE RANDOMIZED OPEN-LABEL STUDY (STRIB-PEP)****Summary**

EudraCT number	2014-001193-34
Trial protocol	ES
Global end of trial date	15 July 2016

Results information

Result version number	v1 (current)
This version publication date	12 September 2025
First version publication date	12 September 2025

Trial information**Trial identification**

Sponsor protocol code	STRIB-PEP
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02198443
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clínic per a la Recerca Biomèdica
Sponsor organisation address	Rosselló 149, Barcelona, Spain,
Public contact	Anna Cruceta, CTU clinical Trial unit- hospital clinic Barcelona, +34 9322754004380, acruzeta@recerca.clinic.cat
Scientific contact	Anna Cruceta, CTU clinical Trial unit- hospital clinic Barcelona, +34 9322754004380, acruzeta@recerca.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	15 July 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 July 2016
Global end of trial reached?	Yes
Global end of trial date	15 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Compare the rate of dropouts from a new pattern of prophylaxis (PEP) post-exposure HIV with a guideline classic 28 days of treatment.

Protection of trial subjects:

The STRIBPEP clinical trial was conducted in accordance with the Declaration of Helsinki and Spanish legislation (Real Decreto 223/2004). All participants provided written informed consent after receiving clear, understandable information. Confidentiality of personal data was strictly maintained, and subjects were identified only by study codes. The study was approved by the relevant ethics committee and regulatory authorities, and participants retained the right to withdraw at any time without prejudice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 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: 157
Worldwide total number of subjects	157
EEA total number of subjects	157

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)	157
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited at the emergency department of Hospital Clínic de Barcelona following potential non-occupational exposure to HIV. A total of 594 individuals were assessed for eligibility, and 157 were randomized after meeting inclusion criteria based on national guidelines.

Pre-assignment

Screening details:

Screening included baseline clinical evaluation and laboratory tests performed within the first 10 days post-exposure. Randomization and treatment initiation occurred immediately after eligibility confirmation. Patients received counselling and prophylaxis for other STIs as per national guidelines.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Elvitegravir/cobicistat

Arm description:

Participants received a single-tablet regimen of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (Stribild®) once daily for 28 days as post-exposure prophylaxis (PEP) for HIV-1.

Arm type	Experimental
Investigational medicinal product name	Tenofovir+Emtricitabine+Cobicistat+Elvitegravir
Investigational medicinal product code	
Other name	Stribild®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Film-coated tablet containing 150 mg elvitegravir, 150 mg cobicistat, 200 mg emtricitabine, and 245 mg tenofovir disoproxil (equivalent to 300 mg tenofovir disoproxil fumarate or 136 mg tenofovir). Administered orally, once daily.

Arm title	Lopinavir/ritonavir
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Arm description:

Participants received lopinavir/ritonavir (Kaletra®) twice daily plus emtricitabine/tenofovir disoproxil fumarate (Truvada®) once daily for 28 days.

Arm type	Active comparator
Investigational medicinal product name	Lopinavir + Ritonavir + Emtricitabine + Tenofovir disoproxil fumarate
Investigational medicinal product code	
Other name	Kaletra®, Truvada®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Lopinavir/ritonavir (Kaletra®) 400/100 mg twice daily (2 tablets of 200/50 mg), plus emtricitabine/tenofovir disoproxil fumarate (Truvada®) 200/245 mg once daily, both taken orally for 28 days.

Number of subjects in period 1	Elvitegravir/cobicistat	Lopinavir/ritonavir
Started	119	38
Completed	79	20
Not completed	40	18
Switched ART	-	2
Adverse event, non-fatal	1	1
HIV positive at day 1	1	-
Lost to follow-up	38	15

Baseline characteristics

Reporting groups

Reporting group title	Elvitegravir/cobicistat
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Reporting group description:

Participants received a single-tablet regimen of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (Stribild®) once daily for 28 days as post-exposure prophylaxis (PEP) for HIV-1.

Reporting group title	Lopinavir/ritonavir
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Reporting group description:

Participants received lopinavir/ritonavir (Kaletra®) twice daily plus emtricitabine/tenofovir disoproxil fumarate (Truvada®) once daily for 28 days.

Reporting group values	Elvitegravir/cobicistat	Lopinavir/ritonavir	Total
Number of subjects	119	38	157
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	33	31	
inter-quartile range (Q1-Q3)	27 to 40	26 to 38	-
Gender categorical Units: Subjects			
Female	6	2	8
Male	113	36	149

End points

End points reporting groups

Reporting group title	Elvitegravir/cobicistat
Reporting group description: Participants received a single-tablet regimen of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (Stribild®) once daily for 28 days as post-exposure prophylaxis (PEP) for HIV-1.	
Reporting group title	Lopinavir/ritonavir
Reporting group description: Participants received lopinavir/ritonavir (Kaletra®) twice daily plus emtricitabine/tenofovir disoproxil fumarate (Truvada®) once daily for 28 days.	

Primary: PEP non-completion and lost to follow-up

End point title	PEP non-completion and lost to follow-up ^[1]
End point description: Proportion of patients who discontinue the initial post-exposure prophylaxis (PEP) regimen for any reason before completing 28 days of treatment. A patient is considered to have discontinued if they die, do not attend the week 4 visit, or switch/stop the study treatment.	
End point type	Primary
End point timeframe: Day 28	

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: Although no formal statistical model was applied in the EudraCT entry, the primary endpoint (PEP non-completion before day 28) was descriptively compared between arms using proportions. The study was exploratory in nature and not powered for formal hypothesis testing. The results are presented as counts and percentages per arm.

End point values	Elvitegravir/cobicistat	Lopinavir/ritonavir		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	38		
Units: Subjects				
Completed	79	20		
Not completed	40	18		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the date of informed consent until the last follow-up visit (week 24).

Adverse event reporting additional description:

Adverse events were collected at each scheduled visit through clinical observation, laboratory tests, and open-ended patient interviews. Serious adverse events were reported within 24 hours to the study monitor and followed until resolution or stabilization.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	Elvitegravir/cobicistat
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Reporting group description: -

Reporting group title	Lopinavir/ritonavir
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Reporting group description: -

Serious adverse events	Elvitegravir/cobicistat	Lopinavir/ritonavir	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 119 (0.00%)	0 / 38 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Elvitegravir/cobicistat	Lopinavir/ritonavir	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	58 / 119 (48.74%)	34 / 38 (89.47%)	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 119 (5.04%)	10 / 38 (26.32%)	
occurrences (all)	6	12	
General disorders and administration site conditions			
Other	Additional description: Other non-serious adverse events not individually specified in the publication.		
subjects affected / exposed	34 / 119 (28.57%)	0 / 38 (0.00%)	
occurrences (all)	34	0	

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	10 / 119 (8.40%)	25 / 38 (65.79%)	
occurrences (all)	10	30	
Nausea			
subjects affected / exposed	8 / 119 (6.72%)	25 / 38 (65.79%)	
occurrences (all)	8	25	

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

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

Limitations: 21% of patients were lost to follow-up at day 1, most participants were MSM (92%) with only 5% women, and limited data were available on partners' HIV status and STIs. HIV testing at ER was not performed due to hospital protocols.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/290912>