



Clinical trial results:

Bictegravir/FTC/TAF for the treatment of primary HIV infection (BIC-PHI trial).

Summary

EudraCT number	2020-000601-89
Trial protocol	ES
Global end of trial date	29 August 2023

Results information

Result version number	v1 (current)
This version publication date	13 September 2025
First version publication date	13 September 2025

Trial information

Trial identification

Sponsor protocol code	BIC-PHI
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04483674
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clinic per a la Recerca Biomèdica
Sponsor organisation address	Villarroel, 170, Barcelona, Spain,
Public contact	AnaCcruceta, Clinical Trial unit (CTU), acruceta@recerca.clinic.cat
Scientific contact	AnaCcruceta, Clinical Trial unit (CTU), acruceta@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	29 August 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 September 2022
Global end of trial reached?	Yes
Global end of trial date	29 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Proportion of patients with rapid ART initiation with Bictegravir/FTC/TAF regimen who reached a VL <50 copies at 48 weeks (FDA snapshot algorithm) in the intention-to-treat (ITT) population.

Protection of trial subjects:

Trial subjects are protected under the Declaration of Helsinki, GCP, and local laws. Informed consent is required, confidentiality is ensured, and participants may withdraw at any time. Ethics committees oversee the study's conduct.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 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: 64
Worldwide total number of subjects	64
EEA total number of subjects	64

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)	64
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

66 subjects screened; 64 enrolled. Exclusion criteria: recent PrEP use, complete seroconversion, active HCV. ART initiated within 72h of diagnosis to ensure early-stage PHI inclusion and assess impact on viral reservoir.

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	BIC/FTC/TAF
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Arm description:

Single-arm: BIC/FTC/TAF regimen (Treatment with bictegravir/emtricitabine/tenofovir alafenamide).

Arm type	Experimental
Investigational medicinal product name	Bictegravir/emtricitabine/tenofovir alafenamide
Investigational medicinal product code	
Other name	BIKTARVY®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

BIKTARVY® is a three-drug fixed dose combination product containing 50 mg of bictegravir (BIC), 200 mg of emtricitabine (FTC), and 25 mg of tenofovir alafenamide (TAF). The recommended dosage of BIKTARVY is one tablet taken orally once daily with or without food in adults for 48weeks.

Number of subjects in period 1	BIC/FTC/TAF
Started	64
Completed	56
Not completed	8
Physician decision	2
Lost to follow-up	6

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial
Reporting group description: -	

Reporting group values	Overall Trial	Total	
Number of subjects	64	64	
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	32		
inter-quartile range (Q1-Q3)	26 to 41	-	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	60	60	
Geographical origin			
Units: Subjects			
Europe	37	37	
Latin-America	22	22	
Other	5	5	

End points

End points reporting groups

Reporting group title	BIC/FTC/TAF
Reporting group description:	
Single-arm: BIC/FTC/TAF regimen (Treatment with bictegravir/emtricitabine/tenofovir alafenamide).	

Primary: Proportion of patients with rapid ART initiation with Bictegravir/FTC/TAF regimen who reached a VL <50 copies at 48 weeks (FDA snapshot algorithm) in the intention-to-treat (ITT) population.

End point title	Proportion of patients with rapid ART initiation with Bictegravir/FTC/TAF regimen who reached a VL <50 copies at 48 weeks (FDA snapshot algorithm) in the intention-to-treat (ITT) population. ^[1]
End point description:	
End point type	Primary
End point timeframe:	
48 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: The primary endpoint—proportion of patients with VL <50 copies/mL at 48 weeks (FDA snapshot, ITT)—is descriptive in nature and aligned with standard virological efficacy benchmarks in HIV trials. Given the single-arm design, no formal hypothesis testing was planned. The endpoint provides clinically meaningful data without requiring inferential statistics.

End point values	BIC/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: copies/mL	52			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the start of treatment until 48 weeks post-initiation.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	BIC/FTC/TAF
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Reporting group description: -

Serious adverse events	BIC/FTC/TAF		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 64 (6.25%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Removal of a rectal foreign body			
subjects affected / exposed	1 / 64 (1.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Worsening of a known cardiopathy			
subjects affected / exposed	1 / 64 (1.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 64 (1.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Perianal abscess			

subjects affected / exposed	1 / 64 (1.56%)		
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	BIC/FTC/TAF		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 64 (65.63%)		
Gastrointestinal disorders			
Diarrhea, etc			
subjects affected / exposed	10 / 64 (15.63%)		
occurrences (all)	10		
Skin and subcutaneous tissue disorders			
Dermatologic			
subjects affected / exposed	6 / 64 (9.38%)		
occurrences (all)	6		
Psychiatric disorders			
Insomnia, headache, anxiety and depression			
subjects affected / exposed	10 / 64 (15.63%)		
occurrences (all)	10		
Infections and infestations			
Mostly upper respiratory viral infections and sexually transmitted infections			
subjects affected / exposed	28 / 64 (43.75%)		
occurrences (all)	28		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 June 2022	Extension of the recruitment period by 12 additional months. Rationale: 1- Increased use of pre-exposure prophylaxis (PrEP), which reduced the number of eligible participants. 2- Decrease in patient availability due to the COVID-19 pandemic.

Notes:

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.

Recruitment was extended due to increased PrEP use and COVID-19 impact. The single-arm design, limited early-stage cases, and exclusion of PrEP users may affect generalizability and statistical power.

Notes: