Clinical trial results:
A Test and Treat strategy in Barcelona: A prospective study in new HIV diagnosis.

Summary

EudraCT number	2019-004837-17
Trial protocol	ES
Global end of trial date	11 May 2023

Results information

Result version number	v1 (current)
This version publication date	17 September 2025
First version publication date	17 September 2025

Trial information

Trial identification

Sponsor protocol code	Biktarvy_Test&Treat

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04416906
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clínic per a la Recerca Biomèdica
Sponsor organisation address	Villaroel, 170, Barcelona, Spain,
Public contact	Berta Torres, Hospital Clínic, +34 9322754004645, btorres@clinic.cat
Scientific contact	Berta Torres, Hospital Clínic, +34 9322754004645, btorres@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	11 May 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 May 2023
Global end of trial reached?	Yes
Global end of trial date	11 May 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the number of patients with the presence of any criteria that contraindicates the start of any antiretroviral regimen within the first week since the HIV confirmation.

Protection of trial subjects:

The study follows the Declaration of Helsinki, ICH-GCP, and applicable EU and national regulations. All participants will sign informed consent before any study procedures. The trial uses an authorized medication (Biktarvy®) within its approved indication, and no additional procedures pose more than minimal risk.

Safety is monitored through scheduled visits and adverse event reporting. SAEs and SUSARs will be reported promptly. Data confidentiality is ensured through pseudonymization and GDPR compliance. Only authorized personnel will access source data for monitoring or audits.

No Data Safety Monitoring Board (DSMB) is established due to the low-risk nature of the study. Civil liability insurance is in place to cover any harm related to participation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 October 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: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	100
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 118 individuals were screened between October 2020 and May 2022. Of these, 100 were enrolled. Reasons for screening failure included exclusion criteria (e.g. recent PrEP use, suspected opportunistic infections) and participant refusal.

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

Arm description:

Participants in this arm received a once-daily fixed-dose combination of bictegravir (50 mg), emtricitabine (200 mg), and tenofovir alafenamide (25 mg) as first-line antiretroviral therapy. Treatment was initiated within 7 days of HIV-1 diagnosis, without waiting for baseline lab results.

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

Dosage and administration details:

This is a fixed dose combination regimen containing 50 mg of Bictegravir + 200 mg of Emtricitabine + 25 mg of Tenofovir alafenamide.
All the subjects will receive one tablet of Biktarvy® every 24 hours during 48 weeks.

Number of subjects in period 1	BIC/FTC/TAF
Started	100
Completed	84
Not completed	16
Physician decision	1
Consent withdrawn by subject	2
Adverse event, non-fatal	2
Lost to follow-up	11

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	100	100	
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)	27 to 38	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	95	95	
Gender Units: Subjects			
Cisgender	84	84	
Transgender	16	16	
Origin Units: Subjects			
Latin	64	64	
America	34	34	
Europe	1	1	
Asia	1	1	

End points

End points reporting groups

Reporting group title	BIC/FTC/TAF

Reporting group description:

Participants in this arm received a once-daily fixed-dose combination of bictegravir (50 mg), emtricitabine (200 mg), and tenofovir alafenamide (25 mg) as first-line antiretroviral therapy. Treatment was initiated within 7 days of HIV-1 diagnosis, without waiting for baseline lab results.

Primary: Proportion of participants with at least one condition making any recommended ART regimen other than BIC/FTC/TAF less appropriate for rapid initiation

End point title	Proportion of participants with at least one condition making any recommended ART regimen other than BIC/FTC/TAF less appropriate for rapid initiation[1]

End point description:

This endpoint assesses the feasibility of using BIC/FTC/TAF as a rapid initiation regimen in newly diagnosed HIV-1 individuals. It measures the proportion of participants who, based on baseline laboratory and clinical data, present at least one condition that would make other guideline-recommended ART regimens less suitable for immediate initiation. These conditions include: HLA B*5701 positivity, HBsAg positivity, M184V mutation, HIV RNA >500,000 copies/mL, eGFR <50 mL/min, and concomitant medications with significant drug–drug interactions.

End point type	Primary

End point timeframe:

Week 4 after ART initiation

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: This endpoint is descriptive and reports the proportion of participants with contraindications to alternative ART regimens. It is summarized with a 95% confidence interval. No formal hypothesis testing was planned, as the aim is to assess feasibility rather than compare treatments.

End point values	BIC/FTC/TAF			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: Subjects	11			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline (week 0) to week 48.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	BIC/FTC/TAF

Reporting group description: -

Serious adverse events	BIC/FTC/TAF		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 100 (5.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Creatinine kinase increase			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Transient ischaemic attack			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Autolytic attempt			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Mycobacterium tuberculosis cervical adenitis			

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 100 (1.00%)		
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	71 / 100 (71.00%)		
Nervous system disorders			
Drowsiness, Headache, etc.	Additional description: Drowsiness 2 (12%) Headache 2 (12%) Insomnia 2 (12%)		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	17		
General disorders and administration site conditions			
Other			
subjects affected / exposed	20 / 100 (20.00%)		
occurrences (all)	20		
Gastrointestinal disorders			
Diarrhea, Nausea, etc.	Additional description: Abdominal pain 2 (10%) Biliary colic 1 (5%) Constipation 1 (5%) Diarrhea 6 (30%) Epigastric pain 2 (10%) Gallstones 1 (5%) Gastro-intestinal disorder 1 (5%) Nausea 5 (25%) Vomiting 1 (5%)		
subjects affected / exposed	9 / 100 (9.00%)		
occurrences (all)	20		
Skin and subcutaneous tissue disorders			
Eczema, Skin reaction, etc	Additional description: Eczema 4 (29%) Folliculitis 1 (7%) Hemorrhoids thrombosed 1 (7%) Kaposis sarcoma 1 (7%) Prurigo nodularis 1 (7%) Rash 1 (7%) Skin reaction 4 (29%) Tinea versicolor 1 (7%)		

subjects affected / exposed occurrences (all)	6 / 100 (6.00%) 14		
Infections and infestations COVID-19, Syphilis, etc.	Additional description: COVID-19 11 (13%) Proctitis chlamydial 10 (12%) Proctitis gonococcal 4 (5%) Syphilis 11 (13%) Tuberculosis 4 (5%)		
subjects affected / exposed occurrences (all)	34 / 100 (34.00%) 84		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 March 2022	Correction of two protocol elements: Clarification that patients receiving non-permitted medication must be withdrawn from the study (previously referred to as "not recommended medication"). Removal of the CESTA questionnaire from the baseline visit; it will now only be conducted at week 48.

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.

The main limitation is the disparity between the protocol and the non-prespecified primary outcomes. Such a significant change indicates evolving standards in HIV treatment, as these findings predominantly align with European and US guidelines.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/39045754