# Study of Bictegravir/Emtricitavine/Tenofovir alafenamide in HIV-1 infected naïve patients using test and treat stategy rapid-initiation model of care: BIC-NOW clinical trial (BIC-NOW)

**First published:** 14/12/2023

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Study | Ongoing

## Administrative details

**EU PAS number**

EUPAS108061

**Study ID**

108126

**DARWIN EU® study**

No

**Study countries**

Spain

**Study description**

The HIV epidemic is not over, according to data of WHO and UNAIDS in 2017, a total of 36.9 million people infected with HIV in the world, 1,8 million people were newly infected with HIV, and 10% of those among children <15 years old. In Spain there are more than 10 new infections diagnosed every day, a 0,2% of world total, with 3381 new infections and a total of 140.000-170.000 are living in Spain with HIV at 2017, 18% of those do not knowing it. In the province of Andalusia, results are better but still high with 574 new infections in 2017 (6.85/100.000 pp) Bictegravir (BIC) is an INSTI commercialized is Spain in a single tablet regimen (STR) associated with TAF/FTC, have a great genetic barrier (so do not need a previous genotypic resistance test to be prescribed) and does not experience differences in effectivity from gender, race, age, CD4 count or plasmatic viral load, no need of HLA study and only creatinine is needed to be prescribed (use is not recommended in patients with CrCl <30 mL/minute) Until now, the only ART capable of that was TAF/FTC/DRV/c, demonstrated in the DIAMOND clinical trial For all the reasons above, the primary objective of this study is to analyze in treatment naïve HIV patients the antiviral activity, using a test and treat strategy, in real life of BIC/FTC/TAF. Secondary, this study aims to evaluate outcomes for implementation of the evidence based test and treat strategy. Secondary clinical objectives are: To evaluate the effect of patient demographics and baseline characteristics on response to BIC/FTC/TAF over time, to asses viral resistance tests in subject meeting confirmed virologic failure, to evaluate antiviral activity, to evaluate the safety and tolerability of BIC/FTC/TAF over time, to analyze subject adherence to the healthcare system.

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**Study status**

Ongoing

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

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**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 30/10/2020

Actual: 13/01/2021

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**Study start date**

Planned: 16/11/2020

Actual: 16/11/2020

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**Date of final study report**

Planned: 31/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GILEAD

## Regulatory

**Was the study required by a regulatory body?**

No

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Clinical trial

**Main study objective:**

To analyze antiviral activity of BIC/FTC/TAF at 24 and 48 weeks in HIV-1-infected, ART-naive subjects, using test and treat strategy.

## Study drug and medical condition

**Medicinal product name**

BIKTARVY

# Population studied

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

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**Estimated number of subjects**

208

# Study design details

**Outcomes**

Proportion of subjects with plasma HIV-1 RNA <50 copies/mL at week 24 AND 48 using FDA Snapshot algorithm. There are secondary clinical outcomes and implementation outcomes. Demographics Full blood haemogram and chemistry Serology Patient reported outcomes (PROs) FAT DEXA

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**Data analysis plan**

Descriptions of the principal variables collected in the study were, for the quantitative variables, measures of central tendencies and dispersion: mean, standard deviation, median, percentiles, and for the qualitative variables, absolute and relative frequencies. To assess the effectivity, subjects response with VL<50copies/mL will be analyzed. Effectivity results will be compared among patients classified as immediate treatment and those classified as fast treatment. At least three analyses will be performed to assess endpoints when every subject completed the week 4, 24 and 48, being the primary analysis at

week 48.

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data sources (types)**

Other

Drug dispensing/prescription data

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No