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)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/108126

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.

Study status

Ongoing

Contact details

Study institution contact

SEQUERA-ARQUELLADAS SERGIO

Study contact

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Primary lead investigator

HIDALGO-TENORIO CARMEN

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/10/2020

Actual: 13/01/2021

Study start date

Planned: 16/11/2020

Actual: 16/11/2020

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

Name of medicine

BIKTARVY

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

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

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

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