An observational cohort study to evaluate the impact of the tenofovir-based single tablet regimens on adherence, quality of life and cost-effectiveness in HIV-1 infected patients (GUESS)

First published: 08/03/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS12725

Study ID

28789

DARWIN EU® study

No

Study countries

Portugal

Study description

GX-PT-177-0143: The primary objective of this study was to prospectively evaluate the impact of tenofovir-based single tablet regimens (STR) on adherence in HIV-1 infected subjects.This was a multicenter, observational study with a control cohort, with retrospective and prospective follow up periods.The study duration from enrolment of the first subject to completion of the 2 years of prospective follow up of the last subject was approximately 5 years.A total of 860 adult subjects infected with HIV-1 was expected to be included in this study (400 in the STRs Cohort and 460 in the Control Cohort). However, only 476 subjects were enrolled.

Study status

Finalised

Research institutions and networks

Institutions

Hospital de Santa Maria, CHLN

Centro Hospitalar Lisboa Norte, EPE (CHLN) – Hospital Santa Maria and Hospital Pulido Valente Portugal, Centro Hospitalar do Porto, EPE (CHP) – Hospital de Santo António Portugal, Centro Hospitalar Lisboa Ocidental, EPE (CHLO) – Hospital

Egas Moniz Portugal, Centro Hospitalar Universitário de Coimbra, EPE (CHUC) – Hospitais da Universidade de Coimbra Portugal, Hospital Beatriz Ângelo (HBA) Portugal, Hospital Professor Doutor Fernando Fonseca, EPE (HFF) Portugal, Hospital Garcia de Horta, EPE (HGO) Portugal, Hospital de Cascais Dr. José de Almeida Portugal, Centro Hospitalar do Baixo Vouga, EPE (CHBV) – Hospital de São Pedro Portugal, Centro Hospitalar de Vila Nova de Gaia / Espinho, EPE (CHVNGE) Portugal

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 20/12/2011

Study start date
Actual: 10/07/2013

Data analysis start date
Actual: 30/05/2018

Date of final study report
Planned: 30/09/2018

Actual: 16/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

Protocol_GX-PT-177-0143_Final Version 4 19Aug2015.pdf (1.64 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Adherence

Data collection methods:

Primary data collection

Main study objective:

To prospectively evaluate the impact of tenofovir-based single tablet regimens (STR) on adherence in HIV-1 infected subjects. Adherence was assessed using the CEAT-VIH, which is an instrument for the assessment of adherence rates to cART in HIV-infected subjects.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

HIV infection WHO clinical stage I

Population studied

Short description of the study population

Adult HIV-1 infected subjects who initiated cART between 1st January 2008 and 30th June 2015 according to EACS Guidelines in force at the time.

Subjects must meet all of the following inclusion criteria:

1. Subjects who give written informed consent.
2. HIV-1 infected subjects, aged 18 years or older at time of introduction of first cART.
3. Availability of complete antiretroviral therapy clinical history and pharmacy refills (pharmacy’s electronic database).
4. Subjects who initiated therapy with a regimen containing one boosted

protease inhibitor (PI/r) plus two Nucleoside Reverse Transcriptase Inhibitors (2NRTI) or one Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI) plus 2NRTI or one integrase inhibitor (INSTI) boosted or not plus 2NRTI, according to the EACS Guidelines in force at the time

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Immunocompromised

Estimated number of subjects

860

Study design details

Outcomes

Adherence:Mean score of CEAT-VIH questionnaire in the subgroup of subjects of the STR cohort who were on tenofovir-based at the time the questionnaire was administered, compared to the mean score of the same questionnaire among subjects in the control cohort. Comparison was performed at enrolment, 12 months and at 24 months, after adjusting for baseline variables and other confounders. Quality of lifeAdherenceEffectiveness, safety and tolerabilityCosts & hospitalization

Data analysis plan

For qualitative data, absolute and relative frequencies were presented. Percentages were based on the total number of subjects with non-missing values unless specified otherwise. Counts for missing values were also tabulated but missing values were not considered in the percentages.For quantitative data, mean, standard deviation, median, 25th and 75th percentiles, minimum, and maximum and number of non-missing cases (95% confidence intervals for parameters of interest) were presented.Comparisons intra-patient for two paired quantitative variables were carried out using linear models or Wilcoxon Sign-Rank test if normality assumption was not accepted.In order to maximize homogeneity between the two cohorts and reduce the impact of treatment-selection bias a propensity score matching (PSM) approach was applied in the statistical analysis.Matched comparisons used conditional logistic regression when the outcome was binary or ordinal.

Documents

Study results

GUESS_CSR_v.2.2_16012019_f-redact.pdf (617.97 KB)

Study publications

Saraiva da Cunha, J.G., Aleixo, M.J., Mansinho, K., Coutinho, D., Pacheco, P., ... Lebre, J.G. Saraiva da Cunha, M.J. Aleixo, K. Mansinho, M. Abreu, M. Doroana, P...

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)

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown