Non-Interventional Real-Life Study of Effectiveness, Safety, Adherence, and Health-Related Quality of Life in Adult Patients receiving Elvitegravir/Cobicistat/Emtricitabine/Tenofovir alafenamide (E/C/F/TAF) or Emtricitabine/Tenofovir alafenamide (F/TAF) or Rilpivirine/Emtricitabine/Tenofovir alafenamide (R/F/TAF) for HIV-1 Infection in Germany (TAFNES)

First published: 05/10/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11010

Study ID

38881

DARWIN EU® study

No

Study countries

☐ Germany

Study description

GS-DE-292-1912: The study enrolled 767 adult (age ≥ 18) treatment-naive and treatment-experienced HIV-1 infected subjects initiating treatment with E/C/F/TAF (318), F/TAF (257) or R/F/TAF (192) in routine care. The study enrolled treatment-naïve and treatment-experienced subjects in each arm. Enrolled subjects were documented for 24 months. The study descriptively analysed effectiveness, safety, resource utilization, and patient reported outcomes for quality of life for the use of E/C/F/TAF, F/TAF or R/F/TAF in routine care.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Multiple centres: 38 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

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Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/09/2015

Actual: 25/09/2015

Study start date

Planned: 04/01/2016

Actual: 04/01/2016

Data analysis start date

Planned: 02/01/2020

Actual: 31/03/2020

Date of final study report

Planned: 30/09/2020

Actual: 09/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

amd-1-GS-DE-292-1912-FINAL-COMPLETE.pdf(1.48 MB)

GS-DE-292-1912-appendix-16.1.1-protocol-amendment 2_f-redact.pdf(1.42 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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate HIV-1 RNA and CD4 cell count changes for patients using E/C/F/TAF, F/TAF or R/F/TAF within a time period of 24 months.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

HIV carrier

Population studied

Short description of the study population

The study will enroll approximately 900 adult (age ≥ 18) treatment-naïve and treatment-experienced HIV-1 infected subjects initiating treatment with E/C/F/TAF, F/TAF or R/F/TAF (300 subjects per arm) in accordance with the respective SmPC in routine care. To evenly represent treatment-naive and treatment-experienced patients the study will enroll in each arm approximately 150 treatment-naive and 150 treatment-experienced subjects.

Subjects must meet all of the following inclusion criteria to be eligible for documentation in this study:

Arm 1 (E/C/F/TAF)

1. HIV-1 infection
2. Signed informed consent
3. ≥ 18 years old
4. Initiating treatment with E/C/F/TAF in accordance with the E/C/F/TAF SmPC

Arm 2 (F/TAF)

1. HIV-1 infection
2. Signed informed consent
3. treatment-naïve subjects ≥ 18 years old
4. treatment-experienced subjects ≥ 50 years old
5. Initiating treatment with F/TAF (in combination with other ARV medication) in accordance with the F/TAF SmPC

Arm 3 (R/F/TAF)

1. HIV-1 infection
2. Signed informed consent
3. ≥ 18 years old
4. Initiating treatment with R/F/TAF in accordance with the R/F/TAF SmPC

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

900

Study design details

Outcomes

To evaluate HIV-1 RNA and CD4 cell count changes for patients using E/C/F/TAF, F/TAF or R/F/TAF within a time period of 24 months, To describe the following: rates of ADRs, motivation for ART initiation in treatment-naïve subjects and factors driving the ART switch to E/C/F/TAF, F/TAF or R/F/TAF in treatment-experienced subjects, adherence and reasons for drug discontinuation during study, physical and mental health related quality of life, health status, and treatment satisfaction, and healthcare resource utilization.

Data analysis plan

For categorical variables: numbers and percentages of patients. For continuous variables: mean, standard deviation (SD), minimum, first and third quartile, median, and maximum. Descriptive statistics summarized demographics and baseline characteristics. The questionnaires scores were calculated according to the algorithms elaborated for these questionnaires. Visit windows were defined to group data in order to generate descriptive statistics across time to assess potential trends in patient reported outcome questionnaires, safety data or

CD4. P-values and/or confidence intervals (95% two-sided) were calculated when considered relevant. Multivariate analyses were conducted to compare the treatment naïve and non naïve treatment groups. Longitudinal analysis were done using mixed models.

Documents

Study results

GS-DE-292-1912-csr-body final_f-redact.pdf(1.89 MB)

Data management

Data sources

Data sources (types)

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

No