Prospective 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 Rilpivirine/Emtricitabine/Tenofovir alafenamide (R/F/TAF) for HIV-1 Infection in France (TARANIS)

First published: 15/11/2016

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16212

Study ID

46011

DARWIN EU® study

No

Study countries

☐ France

Study description

GS-FR-292-4043: This study aimed to describe the effectiveness and safety of E/C/F/TAF and R/F/TAF in treatment-naive and treatment-experienced HIV-1 infected adults as well as adherence, resource utilization, patient reported outcome data about quality of life, health status and treatment satisfaction during daily routine use.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

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

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/03/2016

Actual: 28/03/2016

Study start date

Planned: 03/04/2017

Actual: 13/04/2017

Data analysis start date

Planned: 14/09/2020

Actual: 02/03/2021

Date of interim report, if expected

Planned: 18/06/2018

Actual: 02/07/2018

Date of final study report

Planned: 31/12/2021

Actual: 20/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

protocol GS-FR-292-4043 original 26092016 final.pdf (1.23 MB)

GS-FR-292-4043-appendix-16.1.1-protocol amendment 2_f-redact.pdf (3.58 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:

Other

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

Efficacy

Data collection methods:

Primary data collection

Main study objective:

To assess effectiveness, safety, adherence, health care resource utilization, and patient reported outcomes (PROs) for quality of life of E/C/F/TAF or R/F/TAF use in routine care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

The study will enroll approximately 300 adult (age ≥ 18) treatment-naïve and treatment-experienced HIV-1 infected patients initiating treatment with E/C/F/TAF in
accordance with the approved SmPC in routine care.
Participating study sites are specialized on treating HIV patients. All study sites are located in France.

Inclusion Criteria
Subjects must meet all of the following inclusion criteria to be eligible for documentation in this study:
1) HIV-1 infection
2) Initiating treatment with E/C/F/TAF in accordance with the E/C/F/TAF SmPC
3) ≥ 18 years old
4) Signed informed consent

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

649

Study design details

Outcomes

To evaluate HIV-1 RNA and CD4 cell count changes for patients using E/C/F/TAF or R/F/TAF within a time period of 24 months, Rates of ADRs and serious ADRs, motivation for ART initiation in treatment-naïve subjects and factors driving the ART switch to E/C/F/TAF or R/F/TAF in treatment-experienced subjects, adherence and reasons for E/C/F/TAF or R/F/TAF discontinuation during the study, quality of life, health status, treatment satisfaction using standardized questionnaires, health care resource utilization

Data analysis plan

For categorical variables, numbers and percentages of patients were reported. For continuous variables, mean, standard deviation (SD), minimum, first and third quartile (Q1, Q3), median, and maximum were calculated, together with the total number of observations and the number of missing values. Multivariate analyses were conducted to compare treatment naïve and non-naïve treatment groups. Demographics and baseline measures were potential confounders/effect modifiers for multivariate analyses. Confounders/effect

modifiers and respective adjustments will be addressed in the Statistical Analysis Plan. AEs/SAEs and comorbidities were coded using the Medical Dictionary for Regulatory Activities (MedDRA).

Documents

Study results

GS-FR-292-4043-csr-final-abstract_f-redact.pdf (904.52 KB)

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

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