The Evaluation of Tenofovir Alafenamide Containing Regimens vs. Tenofovir Disoproxil Fumarate Containing Regimens on Renal Outcomes for Prevention, and Treatment of HIV and/or HBV Treatment: a Systematic Literature Review and Meta-analysis

First published: 21/06/2024

Last updated: 11/03/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000194

EU PAS number

EUPAS1000000194

Study ID

1000000194

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Canada
- [ ] China
- [ ] France
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] New Zealand
- [ ] Russian Federation
- [ ] Spain
- [ ] Taiwan
- [ ] United Kingdom

Study description

GS-US-120-7229: This was a non-interventional, retrospective cohort, systematic literature review and meta-analysis in participants in randomized controlled trials or observational cohort studies with tenofovir alafenamide (TAF)-containing regimen and Tenofovir disoproxil fumarate (TDF)-containing regimen for prevention or treatment of Human Immunodeficiency Virus (HIV), and/or treatment of Hepatitis B Virus (HBV).

The primary objective of this study was to compare and quantify the renal outcomes of TAF-containing regimens versus TDF-containing regimens in people who might benefit from pre-exposure prophylaxis (PWBP) and people with HBV, HIV, or HIV/HBV.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Contact details

Study institution contact

Gilead Study Director

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/08/2023

Study start date

Actual: 01/12/2023

Date of final study report

Planned: 02/12/2024

Actual: 24/12/2024

Study protocol

GS-US-120-7229-appendix-16.1.1-Original Protocol_f-redact.pdf(1.26 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 type:

Non-interventional study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TENOFOVIR ALAFENAMIDE

TENOFOVIR DISOPROXIL FUMARATE

Anatomical Therapeutic Chemical (ATC) code

(J05AF13) tenofovir alafenamide

tenofovir alafenamide

Medical condition to be studied

HIV infection

Hepatitis B

Prophylaxis against HIV infection

Population studied

Age groups

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Outcomes

Outcomes: reported renal outcomes, definition of outcomes, method of measurement, time points measured, types of effect measure (e.g., Odds ratio, Risks ratio, etc.) with 95% confidence intervals (if reported) and statistical power (i.e., p-value) (if reported), unit of measurement, number of participants who discontinued study due to renal AEs (if reported)

Documents

Study report

GS-US-120-7229 CSR_Abtract_f-redact.pdf(393.14 KB)

Data management

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes