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

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 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

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

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.

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