A Prospective, Longitudinal, Observational Registry of Truvada for HIV -1 Pre-Exposure Prophylaxis (PrEP) of Adults and Adolescents in Europe

First published: 24/06/2020

Last updated: 16/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43327

EU PAS number

EUPAS35892

Study ID

43327

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Norway
- [ ] Portugal
- [ ] Sweden
- [ ] United Kingdom

Study description

Note: This study was cancelled in agreement with the EMA. GS-EU-276-4487: This study is a prospective, longitudinal, observational, and voluntary participation registry of the real-world usage of Truvada for Pre-Exposure Prophylaxis (PrEP) to prevent Human Immunodeficiency Virus Type 1 (HIV-1) infection in adults and adolescents in Europe. The primary objectives of this study are to: (1) Describe how Truvada for PrEP is prescribed or self-initiated, including the dosing pattern (dose and schedule as daily/intermittent), (2) Characterize the demographics of adults and adolescents who were prescribed or are taking Truvada for PrEP and their HIV risk factors, (3) Characterize the nature and frequency of individual monitoring after initiating Truvada for PrEP, including any available information on adherence, (4) Document any cases of new HIV diagnoses and development of any resistance to Truvada, and selected safety data, and (5) Summarize the characteristics of healthcare professionals (HCPs) who prescribe Truvada for PrEP.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Multiple centres: 45 centres are involved in the study

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
Planned: 31/07/2020

Actual: 02/09/2021

Study start date
Planned: 23/12/2020

Actual: 02/09/2021

Date of final study report
Planned: 31/03/2025

Actual: 02/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

GS-EU-276-4487-appendix-16.1.1-protocol v1.4_f-redact.pdf(1.43 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

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:

The primary objective of this study is to characterize the real-world use of Truvada for PrEP to prevent HIV-1 infections in adults and adolescents in Europe.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is a prospective, longitudinal, observational, and voluntary participation registry designed to characterize the real-world use of Truvada for PrEP to prevent HIV-1 infections in adults and adolescents in Europe.

Study drug and medical condition

Name of medicine

TRUVADA

Medical condition to be studied

Prophylaxis against HIV infection

Population studied

Short description of the study population

The registry population will consist of adults and adolescents who are HIV-1 negative and are taking Truvada for PrEP. Individuals who have either self-initiated Truvada for PrEP or have been prescribed Truvada for PrEP and are being monitored while on Truvada for PrEP will be informed about the registry by their HCPs at one of the participating sites.

Inclusion Criteria:

-HIV-1 negative adults and adolescents who are deemed to be at high risk for acquiring HIV-1

-HIV-1 negative adults and adolescents who provided consent / assent and,

depending on local country regulations, parental or legal guardian permission to participate in the registry
-HIV-1 negative adults and adolescents who are receiving Truvada for HIV PrEP, either as a daily or intermittent regimen, and that are clinically monitored
Exclusion Criteria:
-Individuals currently participating in a clinical study of HIV PrEP

Age groups

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

300

Study design details

Outcomes

Describe how Truvada for PrEP is prescribed or self-initiated, Characterize demographics of individuals who were prescribed or are taking Truvada for PrEP, Characterize the nature and frequency of individual monitoring after initiation, Document new cases of HIV diagnoses and development of any resistance to Truvada, and Summarize characteristics of HCPs who prescribe Truvada for PrEP.

Data analysis plan

Descriptive data analysis will be used to summarize the available data. There are no statistical hypotheses to evaluate. Categorical variables will be reported by proportions and continuous variables will be reported by mean, standard deviation, minimum, median, and maximum. Prescriber characteristics will be summarized. Demographics and clinical characteristics of individuals on Truvada for PrEP will be analyzed. The products prescribed and available prescription details, the frequency of monitoring, and any relevant data on adherence monitoring will be summarized. Seroconversion cases and results of resistance testing will be summarized. Reports of treatment-related renal and bone adverse drug reactions (SADRs and ADRs) will be summarized. Females participants in the registry who are pregnant will also be analyzed. Data will be presented overall, and by age group (adolescents and young adults) and risk factors for HIV transmission.

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