A Prospective, Observational Study of Individuals Who Seroconvert While Taking Truvada for Pre-Exposure Prophylaxis (PrEP)

First published: 12/07/2018

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37077

EU PAS number

EUPAS24374

Study ID

37077

DARWIN EU® study

No

Study countries

☐ Australia

- [ ] Benin
- [ ] Brazil
- [ ] Canada
- [ ] China
- [ ] France
- [ ] Kenya
- [ ] Malawi
- [ ] Netherlands
- [ ] Peru
- [ ] South Africa
- [ ] Tanzania, United Republic of
- [ ] Thailand
- [ ] Uganda
- [ ] United Kingdom
- [ ] United States
- [ ] Zimbabwe

Study description

GS-US-276-0103: This study evaluated HIV-1 RNA and the presence or absence of resistance at baseline and following seroconversion, assessed the frequency of HIV-1 screening and screening method(s) used for evaluation of seroconverters, and collected information regarding whether the seroconverter experienced signs and symptoms of acute HIV-1 infection prior to or at the time of seroconversion.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Multiple centres: 15 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: 30/11/2012

Actual: 30/11/2012

Study start date
Planned: 02/09/2013

Actual: 02/09/2013

Date of final study report
Planned: 30/06/2020

Actual: 20/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences, Inc.

Study protocol

protocol GS-US-276-0103_f-redact.pdf(422.38 KB)

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)

Other study registration identification numbers and links

NCT01902472https://clinicaltrials.gov/ct2/show/NCT01902472

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

This study evaluated HIV-1 RNA and the presence or absence of resistance at baseline and following seroconversion, assessed the frequency of HIV-1 screening and screening method(s) used for evaluation of seroconverters, and collected information regarding whether the seroconverter experienced signs and symptoms of acute HIV-1 infection prior to or at the time of seroconversion.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Medical condition to be studied

Prophylaxis against HIV infection

Population studied

Short description of the study population

HIV-1 negative adults or adolescents (any sex/gender, including transgender) who developed new HIV-1 infection (i.e., seroconverted) while taking Truvada for PrEP.

To be eligible for inclusion in this data analysis, an individual must satisfy all of the following criteria:

1. Evidence of new HIV-1 infection after initiating Truvada for PrEP
2. Individuals may have received Truvada for PrEP from demonstration project or Truvada for
3. PrEP clinical study or they may have received Truvada for PrEP as described in spontaneous or literature reports, always with accompanying results of resistance testing

Exclusion Criteria:

1. Spontaneous or literature report without results of resistance testing

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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)

Estimated number of subjects

150

Study design details

Outcomes

The objectives of the study were to evaluate HIV-1 RNA and the presence or absence of resistance at baseline and following seroconversion, assess the frequency of HIV-1 screening and screening method(s) used for evaluation of seroconverters, and collect information regarding whether the seroconverter experienced signs and symptoms of acute HIV-1 infection prior to or at the time of seroconversion.

Data analysis plan

GS-US-276-0103 collected and analyzed data from individuals who took Truvada® for pre-exposure prophylaxis (PrEP) of sexually acquired HIV-1 infection and who seroconverted (become HIV-1 positive) during follow up. For a minimum of 150 seroconverters, data described: 1) the presence or absence of signs and symptoms of acute HIV infection at the study visit or since the last study visit when seroconversion was identified, 2) the frequency of screening and screening method(s) used for evaluation of the seroconverter, and in general, at that enrollment site, 3) baseline samples from early seroconverters to evaluate HIV-1 RNA and the presence or absence of resistance, and 4) resistance analyses of viral isolates from seroconverters that include population nucleotide sequence analysis followed by ultrasensitive testing (such as ultra-deep sequencing of proviral DNA or allele-specific PCR) if no resistance is identified by population sequencing.

Documents

Study results

GS-US-276-0103-Final-CSR_f-redact.pdf(3.7 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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