An Observational Drug Utilization Study of Stribild® in Adults with HIV-1 Infection

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Study Finalised

Administrative details

EU PAS number

EUPAS6524

Study ID

24887

DARWIN EU® study

No

Study countries

- Belgium
- France
- Germany
- Italy
- Spain
- United Kingdom

Study description

GS-EU-236-0141: A Drug Utilisation Study to assess renal risk minimization measures among Stribild®-treated patients and factors associated with the risk of proximal renal tubulopathy, and its reversibility, including event rates.

Study status

Finalised

Research institutions and networks

Institutions

St Stephen's Aids Trust

Multiple centres: 50 centres are involved in the study

Networks

NEAT-ID, The European treatment network for HIV, hepatitis and global infectious diseases

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosures@gilead.com

Study contact

ClinicalTrialDisclosures@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2014

Actual: 01/04/2014

Study start date

Planned: 31/07/2014

Actual: 04/03/2015

Date of interim report, if expected

Planned: 29/01/2016

Actual: 23/03/2016

Date of final study report

Planned: 31/01/2017

Actual: 15/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences Europe Ltd

Study protocol

GS-EU-236-0141 Final Protocol.pdf (462.56 KB)

amd-2-prot+GS-EU-236-0141-FINAL-COMPLETE.pdf (598.66 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)

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

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess the pattern of renal monitoring and patient management in the clinical setting among subjects treated with STB and compare it to key renal messages in the STB SmPC

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

HIV-1 infected adults who initiate Stribild therapy in 50 participating European clinics participating in the NEAT-ID Foundation across several countries (i.e., Belgium, France, Germany, Italy, Spain, and the United Kingdom). Confirmed diagnosis of HIV-1 infection is required in subjects who are antiretroviral treatment-naïve.

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

1000

Study design details

Outcomes

The rate of proximal renal tubulopathy, The rate of reversibility among subjects with a proximal renal tubulopathy event

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Data analysis plan

Baseline information on subject demographics and other clinical characteristics will be summarized using descriptive statistics (ie, sample size, mean, standard

deviation, median, interquartile range, minimum and maximum) for continuous data and by the numbers and percentages of subjects for categorical data. Summaries will be provided for subjects overall, and for those with incident PRT and reversibility events. Descriptive analyses also will be performed to assess patient management and monitoring per the STB SmPC at baseline and upon STB discontinuation. The risk factors for PRT associated with the use of STB and potentially nephrotoxic concomitant medications will be evaluated by comparing patients with PRT events to those without events. The number and proportion of subjects with Stribild discontinuation due to PRT will be reported with 95% confidence intervals.

Documents

Study results

GS-EU-236-0141-Abstract_f-redact.pdf (362.65 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, Also includes Retrospective patient based data collection of the same patient population as the prospective 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

Unknown