Observational Cohort Study to Assess Rilpivirine (RPV) Utilization According to the European SmPC

First published: 03/06/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5766

Study ID

33836

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Croatia
- [ ] Denmark

- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

Rilpivirine (RPV) is an NNRTI for the treatment of HIV-1 infection in antiretroviral treatment-naïve adult patients with a baseline viral load ≤ 100,000 HIV-1 RNA copies/mL. RPV will be available as two formulations on the European market: a single agent, marketed by Janssen-Cilag International NV, and a fixed-dose combination containing FTC/RPV/TDF, marketed by Gilead Sciences International Ltd. The CHMP has requested further assessment of the development of resistance and whether the product is used in accordance with

the Summary of Product Characteristics (SmPC). The development of resistance and the utilization of RPV according to the SmPC will be assessed through a drug utilization study (DUS) conducted in HIV observational cohorts within Europe. Additionally, the DUS will provide context to the observed rates of virologic failure and development of resistance by describing the treatment outcomes of patients treated with efavirenz (EFV).

Study status

Finalised

Research institutions and networks

Institutions

Eurosida

Networks

EuroSIDA

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Network

Contact details

Study institution contact

Kourtney Davis KDavis24@its.jnj.com

Study contact

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Primary lead investigator

Kourtney Davis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/07/2012

Actual: 11/07/2012

Study start date

Planned: 28/11/2011

Actual: 28/11/2011

Date of final study report

Planned: 31/07/2019

Actual: 18/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Sciences Ireland UC + Gilead Sciences Ireland UC

Study protocol

TMC278-DUS-CTP sep2011.pdf (243.68 KB)

TMC278-DUS-CTP-Amend1 aug2013.pdf (207.2 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:

Secondary use of data

Main study objective:

To assess RPV utilization according to the European SmPC.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

EFAVIRENZ

EVIPLERA

Medicinal product name, other

Edurant

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

Adults living with HIV who initiated therapy with Rilpivirine (RPV) or Efavirenz (EFV)-containing regimens during the study period.

Patients were included in the study if they meet all of the following criteria:
1. Have documented enrollment in the HIV cohort database prior to the start of RPV or EFV-treatment regimens;
2. Have received at least one prescription for RPV-containing regimens or EFVcontaining regimens

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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)

Special population of interest

Immunocompromised

Estimated number of subjects

1600

Study design details

Outcomes

To describe the proportion of patients treated with RPV-containing products in accordance with their SmPCs. To describe treatment emergent RAMs in patients treated with RPV or EFV-containing regimens.To describe virologic failure in patients treated with RPV or EFV-containing regimens. To describe the

demographic characteristics, comorbidities, and medical condition of patients initiating RPV or EFV treatment.To describe ARV treatment status and prior ARV treatment, if any, of patients prior to initiating RPV or EFV treatment.To describe frequency of pre-treatment RAMs for RPV and EFV patients.To describe viral load at start and over the course of RPV or EFV treatment.

Data analysis plan

An evaluation of appropriate use will be conducted through an analysis describing and summarizing the treatment patterns and use of RPV-containing regimens. The analysis will ascertain the number of patients initiating treatment with RPV-containing regimens and the proportion of patients treated in accordance with the SmPCs of RPV-containing regimens. Incidence rates of virologic failure, pre-treatment resistance, and treatment-emergent resistance will be calculated for the RPV- and EFV-treated patients, separately, by dividing the number of events by the total person-exposure time. Relative risks comparing the RPV-containing regimens with EFV-containing regimens and 95% confidence intervals will be calculated and appropriate stratified analyses will be conducted for virologic failure and emergence of treatment resistance. Risk factors associated with virologic failure among those treated with RPV-containing regimens will be assessed using a multivariable Poisson regression model.

Documents

Study results

dus-fina-rpt-amendment Nov19.pdf (302.15 KB)

TMC278-20190618-DUS-Report-final.pdf (983.82 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 source(s), other

EuroSIDA, UK Collaborative HIV cohort (CHIC), with linkage to the UK HIV drug resistance database and the UK Register of HIV Seroconverters, Danish HIV cohort, German HIV-1 Seroconverter cohort, Italian Antiretroviral Resistance Cohort Analysis database (ARCA), French Hospital Database on HIV (FHDH), Cohort of Spanish AIDS Research Network (CoRIS)

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

Unknown