Post-Licensure Safety Study of ISENTRESS™ in a US Managed Care Network

First published: 11/05/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17981

Study ID

17982

DARWIN EU® study

No

Study countries

United States

Study description

The objective of this study is to monitor Health Outcomes of Interest (HOI) in participants with human immunodeficiency virus-1 (HIV-1) infection following treatment with raltegravir. Study participants contributed data to one or more

of 3 cohorts: 1) Historical Cohort: HIV-infected participants treated with antiretroviral therapy in the course of ordinary clinical practice at the clinics and medical centers of Kaiser Permanente (KP) between 1 January 2000 and 12 October 2007 (date of market authorization for raltegravir in USA), 2) Concurrent Cohort: HIV-infected participants treated with a new non-raltegravir antiretroviral therapy in the course of ordinary clinical practice at the clinics and medical centers of KP on or after 12 October 2007, and 3) Raltegravir Cohort: HIV-infected participants treated with raltegravir in the course of ordinary clinical practice at the clinics and medical centers of KP on or after 12 October 2007. Participants could contribute data to more than one cohort, but no overlap in follow-up time was allowed.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution **Pharmaceutical company**

Kaiser Permanente Northern California Division of Research

Contact details

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/04/2008

Study start date

Actual: 31/08/2009

Data analysis start date

Actual: 09/12/2014

Date of final study report
Actual: 09/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NCT01078246

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective of this study is to monitor HOI in participants with human immunodeficiency virus-1 (HIV-1) infection following treatment with raltegravir.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AR) Antivirals for treatment of HIV infections, combinations

Antivirals for treatment of HIV infections, combinations

(J05AX08) raltegravir

raltegravir

Population studied

Short description of the study population

HIV-infected patients treated with RAL.

Raltegravir Cohort Inclusion Criteria:

All HIV-infected patients treated with RAL in the course of ordinary clinical practice at the clinics and medical centers of KP during the study period will be included in the study. The date a patient first receives a dispensed prescription for RAL will serve as the index date for follow-up for that patient. Subjects must have at least one year of continuous membership with KP prior to index date to allow for the assessment of medical and treatment history. For a given HOI, follow-up for a patient treated with RAL will be censored on the date the patient experiences the HOI, death, ends membership with KP, or 90 days after the date patient ends use of RAL.

Raltegravir Cohort Exclusion Criteria:

Exclusion criteria are as follows: (1.) Patients less than 18 years of age; (2.) KP HIV-infected patients who do not receive their medications through the KP pharmacy system; (3.) KP HIV-infected patients who do not receive their laboratory examinations through the KP system; (4.) Patients participating in the phase III or expanded access program. Otherwise, all HIV-infected subjects who meet the continuous membership requirement and are treated with RAL at KP during the study period will be included in the study.

Comparison Cohorts

Historical comparison cohort to assess background incidence of clinical events (primary comparator)

An observational cohort of HIV-infected patients receiving treatment with antiretroviral therapy at KP between January 1, 2000 and the date RAL was licensed in the U.S. (October 12, 2007) will comprise the eligible study population.

Concurrent comparison cohort to assess incidence of clinical events (secondary comparator)

In addition to the historical cohort, the analysis will establish and report results from a post-licensure concurrent comparison cohort of HIV-infected patients receiving treatment with a new antiretroviral therapy at KP after licensure of RAL, and n

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Immunocompromised

Estimated number of subjects

7124

Study design details

Outcomes

1. Incidence of AIDS-defining and non-AIDS-defining malignancy2. Incidence of clinically important hepatic events3. Incidence of clinically important skin events4. Incidence of clinically important muscle events5. Incidence of lipodystropy, 1. Incidence of clinically important cardiovascular events2. Incidence of all-cause mortality

Data analysis plan

Multivariate Cox Proportional Hazard regression will be used to compare the hazard rates among the raltegravir-treated, historical comparison, and concurrent comparison cohorts. Hazard rate ratios (HR) of HOI will be calculated, and regression models that incorporate propensity scores will be used to adjust simultaneously for the potentially confounding effects of selected

variables and comparison group characteristics using CoxProportional Hazard regression.

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Health maintenance organization health records

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