Observational Safety Data Analysis from Routine Follow-up in the EuroSIDA Study of Patients Treated with Raltegravir in a Five-Year Post Authorization Period (MK-0518-058)

First published: 28/04/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18914

EU PAS number

EUPAS17912

Study ID

18914

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Austria
- [ ] Belarus
- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Latvia
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Russian Federation
- [ ] Serbia
- [ ] Slovakia
- [ ] Spain

- [ ] Sweden
- [ ] Switzerland
- [ ] Ukraine
- [ ] United Kingdom

Study description

The purpose of this data analysis is to continue to monitor the safety of raltegravir post-licensure in accordance with the product-specific Risk Management Plan. The main objective of the study was to monitor health outcomes associated with antiretroviral drugs in a population of HIV-infected patients.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

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Institution

Multiple centres: 33 centres are involved in the study

Networks

EuroSIDA Study Group

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

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: 08/04/2008

Study start date

Actual: 05/05/2008

Data analysis start date

Actual: 06/03/2014

Date of final study report

Actual: 06/03/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck & Co., Inc

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

NCT01078233

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

Data collection methods:

Secondary use of data

Main study objective:

The overall objective of this analysis is to investigate the incidence of clinically important medical events following treatment with raltegravir. Incidence rates of medical events and all cause mortality will be determined for raltegravir recipients over the duration of raltegravir exposure and among both a historical and concurrent comparison group.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective analysis of prospective 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

All HIV-infected patients who are 16 years or older and report initiating treatment with raltegravir in the study cohort during the analysis period from 93 clinical centers in 31 European countries, Argentina and Israel.

Patients were included in the RAL patient cohort who:

• started RAL for the first time on or after the 21 December 2007 (RAL authorisation date in the European Union).

• had at least 1 month’s prospective follow-up in this cohort.

• had a CD4 count and a viral load measured within 6 months prior to the start date of RAL.

Patients were included in the historical comparison cohort who:

• started a new antiretroviral drug as part of a cART regimen on or after the 1 January 2006 and before 21 December 2007. The patient must have had no previous exposure to the new drug, including as part of a different co-formulation, e.g. if zidovudine (ZDV) had been previously received as part of Combivir and the patient started Trizivir, ZDV would not be counted as a new drug.

• had at least 1 month’s prospective follow-up in this cohort.

• had a CD4 count and a viral load measured within 6 months prior to the start date of the new drug.

Patients were included in the concurrent cohort not taking RAL who:
• started a new antiretroviral drug other than RAL as part of a cART regimen on or after the 21 December 2007. The patient must have had no previous exposure
to the new drug, including as part of a different co-formulation.
• had at least 1 month’s prospective follow-up in this cohort.
• had a CD4 count and a viral load measured within 6 months prior to the start date of the new drug

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Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Immunocompromised

Estimated number of subjects

6617

Study design details

Outcomes

1. Incidence of malignancy in patients treated with raltegravir2. Incidence of clinically important hepatic events in patients treated with raltegravir3. Incidence of lipodystrophy in patients treated with raltegravir4. Incidence of all-cause mortality in patients treated with raltegravir, 1. Incidence of malignancy

in a post-licensure concurrent comparison cohort2. Incidence of clinically important hepatic events in a post-licensure concurrent comparison cohort3. Incidence of lipodystrophy in a post-licensure concurrent comparison cohort4. Incidence of all-cause mortality in a post-licensure concurrent comparison cohort

Data analysis plan

Incidence rates, and 95% confidence intervals of each pre-specified medical events were tabulated. Multivariate regression was used to compare the incidence rates ofraltegravir versus the historical comparison group. Rate ratios (RR) of adverse events were calculated, and regression models that incorporate propensity scores were used to adjust simultaneously for the potentially confounding effects of selected variables and comparison group characteristics using Poisson regression. Descriptive statistics will be used to describe the heterogeneity in the treatment experience and treatment failure history of raltegravir patients at initiation of therapy.

Data management

Data sources

Data source(s), other

EuroSIDA database

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