Real World Utilisation of Raltegravir Once Daily 1200mg (RETRO Study)

First published: 18/06/2019

Last updated: 27/11/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS30148

Study ID

32479

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study will provide data on patient characteristics and treatment patterns of HIV positive patients initiating raltegravir 1200mg once daily (RAL OD) (2 x 600mg). These data will show how RAL OD is used in the real world setting in

the UK.

Study status

Ongoing

Research institutions and networks

Institutions

Chelsea and Westminster Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

North Manchester Hospital Manchester

Contact details

Study institution contact

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Study contact

LDG_General@merck.com

Primary lead investigator

Marta Boffito

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/07/2018

Actual: 02/07/2018

Study start date
Planned: 01/01/2019

Actual: 01/01/2019

Data analysis start date
Planned: 03/04/2019

Actual: 01/04/2019

Date of final study report
Planned: 30/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD

Study protocol

7651 - RETRO - Protocol - FINAL v0.3 6Nov2018 -CLEAN.pdf (484.29 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

Describe and understand the real world utilisation of raltegravir 1200mg once daily

Study drug and medical condition

Medicinal product name

ISENTRESS

Medical condition to be studied

HIV test positive

Population studied

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

300

Study design details

Outcomes

Patient demographics, baseline clinical and treatment characteristics (co-morbidities, co-medications, AIDS defining illnesses within the last 6 months/ever).ART treatment prior to and initiated with RAL OD. Clinical and treatment characteristics of subjects who remain on RAL OD at the 6 month time point. Laboratory parameters at baseline and 6 months (HIV viral load, CD4 cell count), RAL OD discontinuations at 6 months

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Data analysis plan

Descriptive analysis using summary statistics

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

Retrospective patient records from secondary care settings

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