Current raltegravir use: clinical practice in UK centres (CRICKET)

First published: 30/09/2014

Last updated: 03/05/2016

Study Planned

Administrative details

EU PAS number

EUPAS7379

Study ID

13373

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Rationale: There is little published real world data on the use of raltegravir in the UK. Globally there is also a paucity of real world data on the current use and trends of use of raltegravir. This study will look at patients recently initiated on

raltegravir, with adequate follow-up to determine some basic outcome measures. It is anticipated that this will include a large proportion of patients in the older age group, given use in patients with comorbid conditions and that in some centres 1st line use is uncommon.Primary Objective(s): To describe why, in whom and how raltegravir is being used in clinical practice in 8 treatment centres in the UKStudy Design: Retrospective database analysis. Data will be collected using a standardised tool across all sites. There will be 8 sites in total, four in London and four outside London. Each centre will be asked to review their database and pharmacy records beginning from the 1st of April 2013 and working backwards to include the most recent patients who meet the inclusion criteria. The study will continue reviewing patient records until 40 patients within each centre have a least 12 months of follow up data available. Study Population: HIV-1 infected adults initiating raltegravir as part of antiretroviral treatment (ART) at treatment centres within the UK, on or prior to the 1st of April 2013. Study Duration: 12 monthsExposure and Outcome: To describe the characteristics of patients prescribed raltegravir the following information will be captured: basic demographics, reasons for starting raltegravir, concomitant ARV and non-ARV medications, number of previous regimens, raltegravir resistance data, co-morbidities, viral load and baseline CD4 count. To aid the detection of differences in raltegravir use between centres, each site will be asked to complete a survey assessing local policy and raltegravir use in scenarios including pregnancy, HIV-2 and post exposure prophylaxis (PEP).

Study status

Planned

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

King's College London

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Royal Free Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Kings College Hospital London, Guy's and St Thomas' hospital London, Central and Northwest London NHS foundation trust London, Royal Free hospital London, Heartlands hospital Birmingham,

Western general hospital Edinburgh, Brighton and Sussex university hospital Brighton, North Manchester general hospital Manchester

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Harpal Lamba

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2014

Study start date

Planned: 01/09/2014

Data analysis start date

Planned: 01/12/2014

Actual: 02/02/2015

Date of interim report, if expected
Planned: 06/05/2015

Actual: 06/05/2015

Date of final study report
Planned: 29/05/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Limited

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe why, in whom and how raltegravir is being used in clinical practice in 8 treatment centres in the UK

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective case notes review of a cohort of patients starting raltegravir

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RALTEGRAVIR

Medical condition to be studied

HIV carrier

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

320

Study design details

Outcomes

The primary outcome is a descriptive analysis of the following,a) reason(s) patients were initiated on raltegravirb) demographics and characteristics of raltegravir patientsc) concomitant ARVs being prescribed with raltegravir, Secondary outcome measures include the following, analysis of treatment response, description of comorbidities and non ARV concomitant medications, duration of raltegravir treatment. Analysis will also include questionnaire data focussing on clinic prescribing policy with regard to PEP, HIV-2 and pregnancy.

Data analysis plan

Statistically, only a simple descriptive analyses of the data will be performed. Data analysis will be undertaken on patients with at least 12 months of follow up. For patients with less than 12 months of follow up analysis of baseline characteristics and other available data willbe performed to understand the degree of selection bias within the study population. By including 8 treatment centres we hope to reduce single centre bias. Furthermore, to minimise bias and to ensure a sample population which is representative of UK, site selection

will be based on treatment hubs within areas of high prevalence. Because compared to the rest of the UK London has a disproportionately higher number of HIV-infected individuals, and hence treatment centres, a process of randomisation was carried out in the selection of treatment centres in London. As consecutive eligible patients are to be included, we hope to minimise the possibility of patient selection.

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)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

The majority of data will be obtained by retrospective case notes review. The study also includes a centre level questionnaire focusing on prescribing policy.

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