A Prospective, Observational Drug Utilization Study of Cobicistat in Adults with HIV-1 Infection (GS-US-216-1230)

First published: 16/09/2014

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/15135

EU PAS number

EUPAS7470

Study ID

15135

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Iceland
- [ ] Ireland
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

Study was not feasible due to low uptake of COBI and therefore was waived - Study cancelled.As part of the COBI EU-RMP, this observational drug utilization study was planned 1) to investigate the effectiveness of routine risk minimization measures by determining the rate of use to boost PIs other than ATV or DRV once-daily and concurrent use with contraindicated medications, and the outcomes of such use, and 2) to obtain information on potential drug interactions with COBI

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Gilead Sciences International Ltd

Multiple centres

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Holly Edgar

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/06/2014

Actual: 21/07/2016

Study start date
Planned: 29/07/2016

Actual: 21/07/2016

Data analysis start date
Planned: 29/07/2018

Actual: 21/07/2016

Date of final study report
Planned: 30/12/2018

Actual: 21/07/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences International Ltd

Study protocol

GS-US-216-1230 Final Draft 12Sep2014.pdf(292.07 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)

Other study registration identification numbers and links

Study was waived due to being unfeasible. Study Cancelled

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To assess the rate of off-label use of COBI to boost PIs other than ATV or DRV once-daily and to assess the rate of concurrent use of COBI with contraindicated medications

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

HIV-1 infected adults aged ≥18 years who take COBI up to one month prior to enrollment during Q1 2015 to Q1 2017 and are seen at one of approximately 40 clinical sites in Europe (anticipated to include Austria, Germany, the UK, Denmark, Ireland, Finland, Norway, Sweden, the Netherlands, Belgium, Iceland, and Spain) and Switzerland.

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

500

Study design details

Outcomes

The rate of off-label use of COBI to boost PIs other than ATV or DRV once-daily and the rate of concurrent use of COBI with contraindicated medications, Describe outcomes following off-label use of COBI.Describe rate of use of identified and potential interacting medications with COBI, the rate of suspected drug interactions during use of COBI and the rate of related AEs during use of COBI with identified and potential interacting medications.Describe the frequency of COBI utilization by patients with baseline conditions

Data analysis plan

Rates and 95% CIs of both (a) off label use of COBI with protease inhibitors other than ATV or DRV once-daily, and (b) concomitant use of COBI with contraindicated medications, determined using Poisson regression models, taking into account person time of COBI exposure.

Data management

Data sources

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