Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in People living with HIV (PLWH) initiating ARV regimen CAB+RPV LA in Collaboration with EuroSIDA (215161)

First published: 26/08/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46179

EU PAS number

EUPAS42556

Study ID

46179

DARWIN EU® study

No

Study countries

- [ ] Albania
- [ ] Argentina
- [ ] Austria
- [ ] Belarus
- [ ] Belgium
- [ ] Bosnia and Herzegovina
- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Georgia
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Netherlands
- [ ] North Macedonia
- [ ] Norway
- [ ] Poland

- [ ] Portugal
- [ ] Romania
- [ ] Russian Federation
- [ ] Serbia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] Ukraine
- [ ] United Kingdom

Study description

This prospective cohort study will aim to better understand the population receiving CAB and/or RPV LA containing regimens in a real-world clinical setting. The study will assess usage patterns, adherence, clinical effectiveness and monitor for resistance among virologic failures for whom data on resistance testing are available.

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2020

Actual: 11/12/2020

Study start date

Planned: 27/08/2021

Actual: 28/08/2021

Date of final study report

Planned: 30/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare & Janssen

Study protocol

viiv-215161-protocol-redact.pdf(1.89 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

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:

• Describe CAB LA and/or RPV LA containing regimens usage patterns

• Assess adherence, durability and discontinuation for persons starting regimen

• Assess the clinical effectiveness among PLWH who initiate regimen

• Monitor for resistance and next treatment response among individuals who switched off regimen

• Evaluate the effectiveness of routine risk minimization measures of regimen

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

EDURANT 25 MG - FILM-COATED TABLET

REKAMBYS

REKAMBYS 600 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

REKAMBYS 900 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

VOCABRIA

VOCABRIA 30 MG - FILM-COATED TABLET

VOCABRIA 400 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

VOCABRIA 600 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

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

CABOTEGRAVIR

RILPIVIRINE

RILPIVIRINE HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(J05AG05) rilpivirine

rilpivirine

(J05AX) Other antivirals

Other antivirals

Medical condition to be studied

Human immunodeficiency virus transmission

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

0

Study design details

Outcomes

• Regimen discontinuation

• Durability

• Adherence

• Clinical effectiveness

• Resistance testing

Data analysis plan

Descriptive analyses will summarize the study population exposed to CAB and/or RPV LA. Proportions and multivariable regression models will be used to assess adherence, discontinuation, virologic failure, and resistance among participants with virologic failure for whom data on resistance testing are available.

Data management

Data sources

Data source(s), other

EuroSIDA (34 European countries, and Israel and Argentina)

Data sources (types)

Electronic healthcare records (EHR)

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