A prospective observational cohort study to monitor for hepatotoxicity and regimen discontinuation due to liver related adverse events among People with HIV, initiating Cabotegravir + Rilpivirine regimens (215162)

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Study Ongoing

Administrative details

EU PAS number

EUPAS45568

Study ID

47333

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 monitor for hepatotoxicity and regimen discontinuation due to liver-related adverse events (AEs) following initiation of CAB+RPV regimen in comparison to two DTG based 2 drug regimens (2DR), DTG+RPV and DTG+3TC among PLWH

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

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: 12/12/2020

Study start date

Planned: 01/03/2022

Actual: 18/02/2022

Date of final study report

Planned: 15/06/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Viiv Healthcare

Study protocol

viiv-215162-protocol-orig-redact.pdf(1.3 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

Characterize the rates & risks of hepatotoxicity by estimating incidence of alanine aminotransferase (ALT) elevation & risk factor for elevation, estimating incidence of cases of combined ALT & total bilirubin elevation & risk factor for elevation Estimate number of individuals discontinuing CAB+RPV, DTG+RPV or DTG+3TC due to any reason & discontinuation due to liver-related related adverse events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

CABOTEGRAVIR

RILPIVIRINE

Anatomical Therapeutic Chemical (ATC) code

(J05AG05) rilpivirine

rilpivirine

(J05AJ04) cabotegravir

cabotegravir

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

• Monitor for hepatotoxicity

• Regimen discontinuations due to liver-related AEs

Data analysis plan

Descriptive analyses will summarize the individuals exposed to each of the three proposed ART regimens. Incidence rates of discontinuation of the regimens and hepatotoxicity will be calculated and where sufficient events accrue, multivariate regression will investigate factors associated with the endpoint of interest.

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