‘COMBINE-2’: Real-world evidence for effectiveness of Two Drug Regimen, Antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor (207859)

First published: 26/07/2018

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24990

Study ID

48021

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ France

- [ ] Italy
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 39 centres are involved in the study

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/11/2017

Actual: 20/11/2017

Study start date
Planned: 20/12/2019

Actual: 18/11/2019

Date of final study report
Planned: 31/05/2023

Actual: 30/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-207859-protocol-redact.pdf(836.72 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To assess the effectiveness of 2DR (integrase inhibitor plus a reverse transcriptase inhibitor) and to collect information on the safety of 2DR in terms of drug related adverse events (AEs) and serious adverse events (SAEs) and development of resistance.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multi-site observational study

Study drug and medical condition

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

DOLUTEGRAVIR

RILPIVIRINE

LAMIVUDINE

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

The study population included HIV positive patients aged 18 years or older initiated two drug regimen, antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor in 2014 in Europe.

Inclusion Criteria:

a) a first-line treatment among naïve patients, or

b) a switching option for those with HIV RNA suppression on current treatment (stable switches), or

c) a second-line treatment for those with virological failure (VF) on prior treatment

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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

Other

Special population of interest, other

Patients with HIV transmission

Estimated number of subjects

500

Study design details

Data analysis plan

The primary effectiveness endpoint will be analysed separately for each population (naïve, stable switch, and treatment-experienced with VF) with an intent-to-treat (ITT) approach. 95% CIs of the observed proportion of patients reaching the effectiveness endpoint will be calculated. Changes from baseline in continuous endpoints in each population between baseline and week 48 will be compared by using Wilcoxon's paired test with the ITT population. Descriptive statistics will be generated for the following:– Grade 3 and 4 adverse events– Serious adverse events (SAE)– ART related adverse events (all grades)– Treatment-modifying adverse events (all grades)– AIDS defining event– Death– Study treatments discontinuation

Documents

Study report

Study Report Anonymized 16 Jan 2024.pdf(1.7 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

NEAT-ID Network

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