Abacavir Use and Risk for Myocardial Infarction and Coronary Artery Disease: Meta-analysis of Data from Clinical Trials (207263)

First published: 24/11/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16324

Study ID

42134

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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: 04/11/2016

Actual: 09/11/2016

Study start date
Planned: 01/12/2016

Actual: 30/11/2016

Data analysis start date
Planned: 01/12/2016

Actual: 30/11/2016

Date of final study report
Planned: 30/04/2017

Actual: 06/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-207263-protocol-redact.pdf(164.12 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Meta-analysis

Data collection methods:

Secondary use of data

Main study objective:

To estimate the exposure adjusted incidence rate and relative rate of myocardial infarction (MI) and coronary artery disease (CAD) events reported in subjects treated with abacavir (ABC)-containing combination antiretroviral

therapy (cART) regimens and in subjects treated with non-ABC-containing cART regimens.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

ABACAVIR

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

For the current meta-analysis, studies were identified through the GSK clinical trial repository. Studies that have been conducted since the 2009 meta-analysis, and for which at least the primary objective had been completed by Dec 2016 were eligible. Similar to the previous meta-analysis, only studies that included at least 24 weeks exposure to cART, with ABC in the active treatment or comparator arm, were selected for inclusion in the meta-analysis. All included subjects were at least 18 years of age, and women of child-bearing potential were only included if on contraception to prevent pregnancy. Subjects

in all included trials had been on cART for less than 14 days after their HIV diagnosis – except in ASSURE (EPZ113734) and STRIVING (201147), in which patients were required to have been on at least 6 months of treatment or switched regimens. Three studies (ARIES, ASSERT and HEAT) did not allow patients to have previously taken any nucleoside analog reverse-transcriptase inhibitors (NRTI) and/or non-nucleoside reversetranscriptase inhibitors (NNRTI) and/or protease inhibitors (PI). ARTs taken by subjects prior to entering a GSK/ViiV Healthcare-sponsored study were ignored in this metaanalysis, and cardiac events were not necessarily an exclusion criteria for the clinical trials.

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

20000

Study design details

Outcomes

Occurrence of MI and CAD based on MedDRA high-level terms

Data analysis plan

This meta-analysis will combine data from studies that were randomized to ABC or control, from studies included in a previous meta-analysis (Brothers et al. 2009) as well as from GSK/VH-sponsored studies identified post-2009. Percentages will be based on the frequency of adverse events collected during the conduct of clinical trials. Exposure adjusted incidence rates per 1,000 person-years will be calculated, and Poisson regression models will used to calculate unadjusted relative rates, but no adjustment for confounders will be performed. 95% confidence intervals will be calculated for rates and relative rates.

Documents

Study results

viiv-207263-clinical-study-report-redact.pdf(4.46 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Randomized clinical trials

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