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

First published: 24/11/2016

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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

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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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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