Rates of Suspected Hypersensitivity Reaction in HIV infected Adult treatment populations screened HLA-B*5701 negative prior to commencing Abacavir therapy: Meta-analysis of Data from GlaxoSmithKline and ViiV Healthcare Sponsored Clinical Trials (207831)

First published: 07/04/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18543

Study ID

42161

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A meta-analysis of data previously collected for 12 MAH- sponsored randomized clinical trials (RCTs) from Phase IIb–IV of drug development, conducted since January 2007. Three thousand and sixty three HLA¬B*5701 negative, HIV infected Adult Subjects were exposed to regimens that included abacavir for a minimum of 20 Weeks, as part of these RCTs. In a sub-population of seven of these RCTs, 1,494 such subjects were exposed to either TRIUMEQ, or its equivalent component actives (given as the single active preparation of TIVICAY in combination with KIVEXA), for a minimum of 24 Weeks. Incidence rates of both: Investigator diagnosed, and MAH adjudicated, clinically suspected abacavir hypersensitivity reactions will be estimated. The exposure to an abacavir-containing regimen will be reported. 95% CIs will be based on exact binomial 2-sided confidence intervals. These analyses will be repeated in the sub-population of subjects, who received TRIUMEQ or its equivalent component actives.

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: 31/03/2017

Actual: 23/03/2017

Study start date

Planned: 10/04/2017

Actual: 10/04/2017

Data analysis start date

Planned: 10/04/2017

Actual: 10/04/2017

Date of final study report

Planned: 26/06/2018

Actual: 19/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-207831-protocol-redact.pdf (156.89 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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To estimate the incidence rate of clinically suspected abacavir hypersensitivity reaction cases (both Investigator diagnosed and MAH adjudicated), reported in HLA-B*5701 negative subjects treated with abacavir-containing anti-retroviral 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 SULFATE

LAMIVUDINE

DOLUTEGRAVIR

Medical condition to be studied

Drug hypersensitivity

Population studied

Short description of the study population

HIV-infected adult subjects will be included in this analysis. Only studies that were completed or for which the primary objective was completed, will be included. This analysis will be based on all treated population defined by subjects who received at least one dose of an ABC- containing product (i.e., ABC/3TC or ABC/DTG/3TC) as either randomized IMP or background medication (i.e., randomization was not based on ABC).

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

3063

Study design details

Outcomes

Investigator diagnosed and MAH adjudicated cases of clinically suspected abacavir hypersensitivity reaction

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Data analysis plan

Incidence rates with percentages will be based on the frequency of both: Investigator diagnosed and MAH adjudicated cases of clinically suspected abacavir hypersensitivity reaction occurring during the conduct of clinical trials. 95% CIs will be based on exact binomial 2-sided confidence intervals (CIs). Incidence rate for clinical suspected abacavir hypersensitivity reaction will be repeated in a sub-population of subjects who received TRIUMEQ (or the equivalent components given as the single active preparation of TIVICAY in combination with KIVEXA).

Documents

Study results

viiv-207831-clinical-study-report-redact.pdf (791.87 KB)

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 and non-randomized controlled 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