Rates of Suspected Hypersensitivity Reaction to Abacavir and Associated Rates of HLA-B*5701 Testing (206206)

First published: 21/07/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS14290

Study ID

42114

DARWIN EU® study

No

Study countries

☐ United States

Study description

Rates of suspected hypersensitivity reaction (HSR) associated with the use of abacavir (ABC) and associated rates of HLA-B*5701 testing in HIV positive patients living in the U.S. who have been exposed to ABC as part of an antiretroviral therapy (ART) regimen will be evaluated utilizing prospectively-collected electronic medical record (EMR) data obtained from the Observational Pharmaco-Epidemiology Research & Analysis (OPERA®) Observational Database

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Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

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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: 14/06/2016

Actual: 14/06/2016

Study start date

Planned: 29/07/2016

Actual: 23/07/2016

Data analysis start date

Planned: 29/07/2016

Actual: 23/07/2016

Date of final study report

Planned: 30/03/2018

Actual: 30/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-206206-protocol-redact.pdf(141.35 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

Observational cohort analysis

Data collection methods:

Secondary use of data

Main study objective:

To describe the baseline demographic and clinical characteristics of HIV+ patients initiating an abacavir-based ART regimen, the annual incidence rates and cumulative frequencies of HLA-B*5701 testing, and the annual incidence rates and cumulative frequencies of suspected hypersensitivity reaction among abacavir-exposed patients before and after June 15, 2008.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive 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

The study sample will be identified from the OPERA Observational Database for analysis. HIV-1 positive patients initiating abacavir-containing treatment for the first time between 1/1/1999 and 1/1/2016 will be included in the study sample if they meet the following inclusion criteria:

1) At least 13 years of age at the index date.

2) Continuous clinical activity in the year prior to abacavir initiation, defined as at least one clinic visit.

3) Continuous clinical activity in the year following abacavir initiation, defined as at least one clinical contact (visit or telephone contact).

Age groups

Adolescents (12 to < 18 years)

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

16000

Study design details

Outcomes

• Diagnosis of suspected hypersensitivity reaction to abacavir (HSR) • Documentation of HLA-B*5701 testing and timing of the test (before or after starting ABC containing regimen)• Exposure to abacavir post positive HLA testing

Data analysis plan

Descriptive analyses will be performed for demographic and clinical variables of interest. Multivariable analyses will be used to produce rates of suspected HSR diagnoses by HLA time period.

Documents

Study results

viiv-206206-clinical-study-report-redact.pdf(5.94 MB)

Data management

Data sources

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