Abacavir Usage Patterns and Trends in Hypersensitivity Reactions (HSR) in the EuroSIDA cohort (206307)

First published: 22/02/2017

Last updated: 18/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17919

Study ID

48247

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Austria
- [ ] Belarus
- [ ] Belgium

- [ ] Bulgaria
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Latvia
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Russian Federation
- [ ] Serbia
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] Ukraine
- [ ] United Kingdom

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

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Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/10/2016

Actual: 28/10/2016

Study start date
Planned: 24/02/2017

Actual: 23/02/2017

Data analysis start date
Planned: 24/02/2017

Actual: 23/02/2017

Date of final study report
Planned: 11/07/2017

Actual: 18/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-206307-protocol-redact.pdf(392.93 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 treatment utilization patterns of abacavir (ABC) and to describe the cumulative frequency, incidence and factors associated with ABC discontinuation due to any reason and due to hypersensitivity reactions (HSR)

among persons initiating ABC as part of a cART regimen after 1/1/2009

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective 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

Patients aged 16 years or older living with HIV and HIV/Hepatitis C co-infection receiving combination antiretroviral therapy (cART) identified from the EuroSIDA cohort.

Inclusion criteria:

• Individuals from the EuroSIDA cohort over the age of 16 at enrolment

receiving cART (at least 3 drugs from any class, excluding ritonavir) at some point after 1/1/2009 will be eligible for inclusion (Objective 1). Objective 2 will further require all individuals to have initiated ABC after 1/1/2009.
• Drug exposure prior to EuroSIDA enrolment cannot be assessed, and will not be considered for the inclusion criteria.

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

Other

Special population of interest, other

Patients with HIV transmission

Estimated number of subjects

20000

Study design details

Outcomes

Receipt of ABC and ABC discontinuation

Data analysis plan

• Descriptive statistics will be used to summarize outcomes of interest and risk factors as appropriate• Baseline characteristics will be compared among patients who remain on ABC, discontinue due to any reason, and discontinue due to HSR using chi-squared tests/Fisher’s exact test and Kruskal-Wallis tests as appropriate • Factors associated with ABC initiation and HSR-related discontinuation will be investigated using Poisson models with generalized estimating equations to control for inclusion of repeated events• Cumulative frequencies of time to discontinuation for any reason and due to HSR will be calculated using survival methods and displayed in KM plots• Sensitivity analyses will be conducted for all discontinuations of ABC occurring within the first 6 weeks and reported to be due to any toxicity

Documents

Study results

viiv-206307-clinical-study-report-redact.pdf(1.94 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective observational cohort study

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