# A Prospective Observational Cohort Study to Monitor and Compare the Occurrence of Hypersensitivity Reaction and Hepatotoxicity in Patients Receiving Dolutegravir (with and without Abacavir) or other Integrase Inhibitors (with or without Abacavir) (201177)

**First published:** 08/10/2014

**Last updated:** 23/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS7597

**Study ID**

36277

**DARWIN EU® study**

No

**Study countries**

Denmark

France

United Kingdom

**Study description**

This is a five year-long non-interventional, prospective cohort study nested within the EuroSIDA study, a prospective observational cohort study of more than 18,200 patients followed in 107 hospitals in 31 European countries, plus Israel and Argentina. The study population will include HIV positive patients over the age of 16 years from EuroSIDA clinical sites, who are new users of dolutegravir (DTG) or other integrase inhibitors with and without abacavir (ABC). Following initiation of DTG with ABC based antiretroviral regimen (DTG as Triumeqä, the fixed dose combination of DTG/ABC/lamivudine) or DTG without ABC ( DTG as Tivicayä) or regimens containing other integrase inhibitors raltegravir (RAL), elvitegravir (EGV) with or without ABC, the study will aim to a) Monitor and compare hypersensitivity reaction, b) Monitor and compare hepatotoxicity, and c) Monitor and compare severe skin rash among all patients discontinuing DTG or other integrase inhibitor regimens for any reason.

**Study status**

Finalised

## Research institutions and networks

## Institutions

### EuroSIDA

## Networks

### EuroSIDA

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Network**

## 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: 30/09/2014

Actual: 30/09/2014

**Study start date**
Planned: 30/09/2014

Actual: 30/09/2014

**Date of interim report, if expected**
Actual: 22/01/2016

**Date of final study report**
Planned: 30/04/2020

Actual: 01/04/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Study protocol

201177-protocol-redact.pdf (554.73 KB)

viiv-201177-protocol1-redact.pdf (85.82 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

To describe the incidence of and characteristics of those who develop hypersensitivity skin reactions, hepatotoxicity, and severe skin rash

## Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

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

DOLUTEGRAVIR

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**Medical condition to be studied**

Hypersensitivity

Hepatotoxicity

Rash

# Population studied

**Short description of the study population**

The study population includes HIV positive individuals over the age of 16 years from EuroSIDA clinical sites, who are new users of DTG or users of other integrase inhibitor regimens (RAL and EVG).

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**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)

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**Special population of interest**

Immunocompromised

**Estimated number of subjects**

10000

## Study design details

**Outcomes**

Hypersensitivity skin reactions, hepatotoxicity, and severe skin rash

**Data analysis plan**

There are 4 patient groups: A) patients that start DTG and ABC based regimen, B) patients that start DTG based regimen without ABC, C) patients that start other integrase inhibitor based regimen RAL and EGV with ABC, D) patients that start other integrase inhibitor based regimen (RAL and EGV) without ABC. Demographics and clinical history will be collected. Descriptive statistics will be used to describe patient characteristics and event frequency. Logistic regression will be used to assess the risk for the events of interest following use of DTG compared to ABC and other integrase inhibitors.

## Documents

**Study results**

viiv-201177-clinical-study-report-final-redact.pdf (1.94 MB)

**Study report**

viiv-201177-clinical-study-report-redact.pdf (1.49 MB)

viiv-201177-clinical-study-report-redact-v02.pdf (1.04 MB)

viiv-201177-clinical-study-report1-redact.pdf (1.31 MB)

**Study, other information**

viiv-201177-clinical-study-report-redact-v02.pdf (1.04 MB)

viiv-201177-clinical-study-report1-redact.pdf (1.31 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 source(s), other**

EuroSIDA Denmark

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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**

Unknown