# An Evaluation of Weight Gain in Patients Treated with Dolutegravir vs. Other Core Agents (208943)

**First published:** 11/01/2019

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS27523

**Study ID**

42173

**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**

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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: 14/12/2017

Actual: 14/12/2017

**Study start date**
Planned: 18/01/2019

Actual: 18/01/2019

**Data analysis start date**
Actual: 01/05/2019

**Date of final study report**
Planned: 30/08/2019

Actual: 07/10/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Study protocol

viiv-208943-protocol-redact.pdf(1.39 MB)

## 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 topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**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

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**Main study objective:**

To describe BMI categories, weight, lipid levels, and lipodystrophy among new users of DTG and other INSTIs at core agent initiation and at 6, 12, and 24 months after core agent initiation and to estimate the association between specific core agent initiation and changes in BMI at 6, 12, and 24 months after core agent initiation

## 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**

Human immunodeficiency virus transmission

# Population studied

**Short description of the study population**

The analysis population will be identified from the OPERA Observational Database according to the inclusion criteria defined below.

Primary population

1) A diagnosis of HIV-1, a positive HIV-1 Western Blot, or a positive HIV-1-specific ELISA; and a detectable HIV-1 viral load test

2) At least 18 years of age at the index date

3) Male or female patients

4) Prescribed DTG, RPV, RAL, BIC, EVG/c and DRV(/r/c) as part of a 3-drug regimen for the first time between 01AUG2013 and 31DEC2017

5) Not exposed to >1 core agent of interest concurrently

Subjects with the following criteria will be excluded from the study sample:

1) HIV-negative

2) A diagnosis of HIV-2, a positive HIV-1/HIV-2 Multispot, a positive HIV-2-specific ELISA, a positive HIV-2 Western Blot or a detectable HIV-2 viral load test

3) Women who are considered pregnant at the index date

4) Transgender patients (potential for weight changes due to hormone use)

Secondary population

The study population for the secondary objectives will be a subset of the

primary study population meeting the following additional inclusion criteria:
1) Patients switching to DTG, RPV, RAL, BIC, EVG/c or DRV(/r/c) as part of a 3-drug regimen for the first time between 01AUG2013 and 31DEC2017 (excluding ARTnaïve patients)
2) Patients with a viral load <200 copies/mL at last viral load test prior to switch to core agent of interest

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**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)

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**Special population of interest**

Immunocompromised

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**Estimated number of subjects**

15000

# Study design details

**Data analysis plan**

Descriptive statistics will be used to summarize baseline demographic and clinical characteristics, as well as weight, lipid, and lipodystrophy outcomes at each time point (6,12, and 24 months). Pairwise comparisons will be made between DTG and other core agents. Adjusted linear regression models will be used to assess the association between core agent and mean changes in BMI at 6, 12, and 24 months. Baseline variables meeting the definition of a confounder will be included in the adjusted models, and will be selected a priori. The

analysis will be stratified by baseline BMI categories (underweight, normal weight, overweight, obese).

## Documents

**Study results**

viiv-208943-clinical-study-report-redact.pdf(5.71 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