DOLOMITE NEAT ID Network Study: A prospective, multi-site observational study to define the safety and effectiveness of Dolutegravir use in HIV positive pregnant women (208759)

First published: 30/05/2018

Last updated: 17/09/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS24237

Study ID

41940

DARWIN EU® study

No

Study countries

Belgium

France

Italy
Poland
Portugal
Spain
Ukraine
United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/11/2017

Actual: 20/11/2017

Study start date
Planned: 18/11/2019

Actual: 18/11/2019

Date of final study report
Planned: 30/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Viiv Healthcare

Study protocol

viiv-208759-protocol-redact.pdf (249.71 KB)

viiv-208759-protocol1-redact.pdf (1.55 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To describe pregnancy and birth outcomes of pregnant women taking dolutegravir.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective patient-based data collection

Study drug and medical condition

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

ABACAVIR

DOLUTEGRAVIR

LAMIVUDINE

RILPIVIRINE

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

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

Pregnant women

Estimated number of subjects

250

Study design details

Outcomes

Pregnancy outcomes include spontaneous abortion, induced abortion, still births, multiple births, type of delivery and maternal viral load (VL) at delivery. Birth outcomes include birth defects and other routinely collected data at birth such as gestational age, birth weight, APGAR score and infant’s HIV status. To provide descriptive analysis of all drug related AEs and SAEs related with the regimen used. To describe rate of DTG discontinuation in pregnant women, including reasons and VL at discontinuation and viral suppression during each of the trimesters where possible.

Data analysis plan

Descriptive statistics will be generated for the following:

– Characteristics
– ARV history and concomitant medication
– Comorbidities
– Trimester of DTG initiation and exposure
– Drug related AEs and SAEs
– Incidence of DTG discontinuation
– VL in each trimester, at delivery and at DTG discontinuation
– Maternal and child outcomes

Analyses will be conducted to assess if there are any associations between DTG

exposure and outcomes for pregnancy and birth using Logistic regression and Cox proportional-hazards models. Potential confounding factors will be included to determine whether they change the odds ratio (OR) or the hazard ratio (HR) for DTG exposure by at least 10% in any of the models.

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

NEAT-ID Network

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