DARWIN EU® - Use of antiretroviral therapies in paediatric patients

First published: 09/04/2025

Last updated: 23/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000545

Study ID

1000000545

DARWIN EU® study

Yes

Study countries

Germany

Norway

Spain

United Kingdom

Study description

Human immunodeficiency viruses (HIV) are retroviruses that can cause acquired immunodeficiency syndrome (AIDS), a condition that leads to progressive failure of the immune system making an individual vulnerable to opportunistic infections and cancers.(1-3)
The optimisation of HIV treatment has been facilitated by a long-term joint collaborative effort between international organizations, academic institutions, innovator and generic manufacturers and other stakeholders, particularly over the last decade.
The WHO PADO initiative for instance marks progress and discusses also pediatric needs. Several FDCs have been authorised for use in pediatric patient in the latest years.
This study is intended to help the assessment of a current request for a pediatric investigation plan (PIP) waiver and future similar requests, submitted under the assumption that studies in pediatrics are not possible as HIV infection is very low in this population and that the treatments needs of such patients are already met by existing medications in first line.
To support this paediatric waiver request, real-world data (RWD) from prescription data from Germany and Spain indicating very low number of children living with HIV in EU countries was submitted. And although there may be very few young patients living with HIV infection in the EU, it is relevant for the PDCO to know more about prevalent cases of HIV in in this population and better understand prescription patterns in various age groups and understand the prevalence of the use of fix-dose combination (FDC) products.
This study will establish the prevalence of HIV infection amongst pediatric patients as well as the prevalence and incidence of antiretroviral therapy within this pediatric population particularly for FDC products, to estimate the current utilisation of some active substances.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | **Educational Institution** | **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Norway

Portugal

Spain

Sweden

United Kingdom

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Guido van Leeuwen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/11/2024

Actual: 27/11/2024

Study start date

Planned: 04/02/2025

Actual: 01/04/2025

Date of interim report, if expected
Planned: 30/05/2025

Date of final study report
Planned: 01/09/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-020_Paediatric HIV_V3.pdf (758.76 KB)

DARWIN EU_Protocol_P3-C1-020_Paediatric HIV_V5.0_Amendment.pdf (1013.96 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This is a descriptive population-level epidemiology study and population-level drug utilisation study (DUS).

Main study objective:

1. To describe the prevalence and incidence of HIV in the paediatric general population in a sample of European countries (Spain, Germany and Norway), overall and stratified by sex, age group (0-<1, 1-<2, 2-<5, 5-<12, 12-<18) and calendar year

2. To describe the prevalence and incidence of use of HIV-specific medication in the paediatric HIV population in a sample of European countries (Germany and Norway) particularly fixed-dose combinations, overall and stratified by sex, age group (0-<1, 1-<2, 2-<5, 5-<12, 12-<18) and calendar year.

3. To describe the prevalence and incidence of use of HIV-specific medication in the paediatric general population in a sample of European countries (Germany, Norway, and the United Kingdom) particularly fixed-dose combinations, overall

and stratified by sex, age group (0-<1, 1-<2, 2-<5, 5-<12, 12-<18) and calendar year.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AE) Protease inhibitors

Protease inhibitors

(J05AF) Nucleoside and nucleotide reverse transcriptase inhibitors

Nucleoside and nucleotide reverse transcriptase inhibitors

(J05AG) Non-nucleoside reverse transcriptase inhibitors

Non-nucleoside reverse transcriptase inhibitors

(J05AJ) Integrase inhibitors

Integrase inhibitors

(J05AR) Antivirals for treatment of HIV infections, combinations

Antivirals for treatment of HIV infections, combinations

(J05AX09) maraviroc

maraviroc

(J05AX07) enfuvirtide

enfuvirtide

(J05AX29) fostemsavir

fostemsavir

(J05AX31) lenacapavir

lenacapavir

(V03AX03) cobicistat

cobicistat

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

The study population will include all individuals observed in one of the participating data sources during the study period (1st January 2010 to 31st December 2024) and having at least 1 year of database history.
For children within the age group of 0-<2 years, the need to have 365 days of prior database history will be dropped.

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Study design details

Setting

This study will use routinely collected health data from 4 databases in the DARWIN EU® network of data
partners from 4 countries. All databases were previously mapped to the OMOP CDM.

Data source

• Base de Datos para la Investigacíon Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain
(objective 1)

• InGef Research Database (InGef RDB), Germany (all 3 objectives)

• Norwegian Linked Health Registry data (all 3 objectives)

Outcomes

The outcome of this study will be the prevalence and incidence of a HIV diagnosis.

In InGef RDB, HIV diagnoses consist of both inpatient and outpatient diagnoses. For outpatient HIV diagnoses in InGef RDB, patients are required to have 2 HIV diagnoses in a year for it to count as an actual diagnosis, since that criterion is commonly used in analyses of German claims data to indicate a higher degree of diagnostic validity compared to patients with a single diagnosis.

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)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Norwegian Linked Health registry at University of Oslo

UK National Neonatal Research Database

InGef Research Database

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown