European Pregnancy and Pediatric HIV Cohort Collaboration (EPPICC) study assessing the safety and efficacy of Kaletra oral solution in children aged 14 days to 2 years with HIV-1 infection in Europe

First published: 02/06/2020

Last updated: 12/12/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS32607

Study ID

48122

DARWIN EU® study

No

Study countries

Belgium

Denmark

Greece
Ireland
Italy
Poland
Spain
United Kingdom

Study description

This study describes the characteristics of children aged less than 2 years of age while treated with Kaletra oral solution at or after the approval date of 26 July 2017 in the European Medicines Agency (EMA) scope of authority within Europe.

The study also assesses the appropriateness of Kaletra oral formulation dose for weight or body surface area while under 2 years and the safety and tolerability of Kaletra in children under 2 years of age by describing adverse events experienced while on Kaletra, in particular in relation to propylene glycol or ethanol toxicity.

In addition, the study also assesses the immune and virological response to Kaletra-containing therapy and the incidence and reasons for discontinuation of Kaletra.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 8 centres are involved in the study

Networks

PENTA & EPPICC

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/12/2018

Study start date

Actual: 01/01/2019

Date of final study report
Planned: 30/06/2022

Actual: 15/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p19106-protocol-pmos_Redacted.pdf (3.58 MB)

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)

Other study registration identification numbers and links

P19-106

Methodological aspects

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

1. Describe characteristics of all children treated with Kaletra (including off-label use) in the EPPICC network in the EMA countries within Europe at or after approval date 26 July 2017.
2. Assess appropriateness of Kaletra dose for weight or body surface area using AbbVie Kaletra SmPC as reference. 3. Evaluate safety and tolerability of Kaletra.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

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

LOPINAVIR

RITONAVIR

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

Children aged 14 days to 2 years with HIV-1 infection treated with Kaletra (lopinavir/ritonavir) oral solution identified from the 8 cohorts across 7 European countries.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Immunocompromised

Other

Special population of interest, other

Patients with HIV transmission

Estimated number of subjects

14

Study design details

Outcomes

Adverse events, including SAEs and AESIs.

Data analysis plan

Data from EPPICC will be summarized using descriptive statistics for the set of all patients and for each of the 4 groups described below. Due to the expected small sample size, graphic summary of individual patient response (e.g. CD4 and HIV-1 RNA viral load over time on Kaletra) may be explored.

Patients will be categorized to a group based on their age, weight (or body surface area where height data are available), dose, and dosing frequency on the day of first reported Kaletra exposure.

The 4 groups are as follows:

Group 1: Licensed: patients 14 days to < 2 years of age initiating on a licensed dose

Group 2: Unlicensed: patients 14 days to < 2 years of age initiating on an unlicensed dose

Group 3: Patients < 14 days of age

Group 4: Patients 14 days to < 2 years of age with missing weight and/or dose data at Kaletra initiation

Documents

Study results

P19-106 CORRECTED REPORT_Abstract_Redacted.pdf (301.88 KB)

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

Pooled analysis of pseudonymized individual patient clinical and laboratory data from the European Union (EU) cohorts participating in the EPPICC pharmacovigilance program (confirmed to have eligible patients, as of August 2019).
Other EU cohorts within EPPICC who may have eligible patients in the future.

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