

Pharmacovigilance study to define the long term safety profile of etravirine in HIV-infected children and adolescents in Europe

First published: 08/03/2016

Last updated: 02/07/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS12694

Study ID

28451


DARWIN EU® study

No










Study countries

 Belgium

 Germany

 Ireland

 Italy

-  Poland
 -  Portugal
 -  Romania
 -  Russian Federation
 -  Spain
 -  Sweden
 -  Switzerland
 -  Thailand
 -  United Kingdom
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Study description

Etravirine (ETR, Intelence®), a non-nucleoside reverse transcriptase inhibitor, is indicated in Europe for use in antiretroviral treatment experienced patients aged ≥ 6 years. Little is known about the “real life” use and safety of ETR in the European population of HIV-infected children and adolescents. The Committee for Medicinal Products for Human Use (CHMP) has highlighted the need for a post-marketing surveillance study of ETR use in the paediatric population. Janssen-Cilag International NV has approached the PENTA Foundation/ European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) about establishing such a study in HIV-infected children and adolescents living in Europe. The aim of this study is to collect long-term safety data on ETR use in children and adolescents with HIV infection in a “real world” setting in Europe. The objectives include describing incidence of serious and non-serious adverse events while on ETR and off-label use of ETR in children. This is an observational study involving the pooled analysis of individual patient data from prospective cohort studies participating in the EPPICC pharmacovigilance programme. In recent years this programme has expanded to include collaborating cohorts in Thailand and South Africa.

Study status

Finalised

Research institutions and networks

Institutions

Medical Research Council (MRC) Clinical Trials Unit
at UCL on behalf of EPPICC/PENTA

Networks

European Pregnancy and Paediatric HIV Cohort
Collaboration (EPPICC)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ali Judd

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/03/2013

Study start date

Actual: 31/01/2014

Date of final study report

Planned: 03/09/2018

Actual: 16/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag International NV

Study protocol

[TMC125-EPPICC-CTP.pdf](#) (328.09 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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The objectives are to describe:1) clinical characteristics of patients at start of ETR2) incidence of grade 3 and 4 adverse events for key laboratory markers by duration on ETR3) incidence of clinical serious and non-serious adverse events considered to be causally related to ETR 4) characterise reasons for discontinuation of ETR5) off-label use of ETR in children

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Perinatal HIV infection

Population studied

Short description of the study population

All HIV-infected children and adolescents with current or previous use of Etravirine (ETR) treatment (excluding in utero exposure), regardless of clinical stage, and who were aged < 18 years at commencement of ETR treatment were included in the study.

Age groups

- Children (2 to < 12 years)
 - Adolescents (12 to < 18 years)
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Special population of interest

Immunocompromised

Estimated number of subjects

100

Study design details

Data analysis plan

Standard descriptive statistics will be used to summarise the data.

Demographic and baseline disease characteristics (eg sex, ethnic group, mode of infection, ever AIDS diagnosis) as well as antiretroviral therapy exposure (eg age starting any ART, age starting ETR, ART duration before ETR, viral load and CD4 at ETR start, other drug classes prescribed with ETR, and median estimated months and total patient years on ETR) of children taking ETR will be described. Laboratory toxicity data for periods on ETR will be summarised by duration of time on ETR (for example, <12 months, 12-24 months, >24 months). Rates of events for children on the licensed dose will be presented along with 95% confidence intervals, by DAIDS grade. Additional descriptive

analyses will be presented on an individual patient basis for all patients with a grade ≥ 3 test result whilst on ETR.

Documents

Study results

[TMC125-EPPICC_PENTA_Annual_Report_2018.pdf](#) (667.95 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

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