

An observational study on growth in HIV-infected children and adolescents on antiretroviral therapy in Europe, with special reference to darunavir (TMC114-EPPICC)

First published: 20/05/2015

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Study

Finalised

Administrative details

EU PAS number

EUPAS9708

Study ID

20959

DARWIN EU® study

No

Study countries

Belgium

Denmark

- France
 - Germany
 - Greece
 - Italy
 - Netherlands
 - Poland
 - Portugal
 - Romania
 - Russian Federation
 - Spain
 - Sweden
 - Switzerland
 - Thailand
 - Ukraine
 - United Kingdom
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Study description

To what extent is the height of HIV-infected children in Europe aged <18 years affected by exposure to darunavir-based ART regimen? The objectives of this study are to: (i) describe the characteristics of HIV-infected children aged <18 years in Europe initiating treatment with a combination ART (cART) regimen and ever taking a darunavir containing regimen including a descriptive summary of their drug utilization data, (ii) describe change in height for age z-score (HAZ) pre- and post-darunavir exposure in these children, (iii) compare the change in HAZ in those taking a darunavir-containing regimen to those taking other non-darunavir containing regimens (if a cohort with similar demographic and clinical characteristics to those taking darunavir can be identified), while adjusting for potential confounding factors including pre-regimen HAZ. The characteristics of the children taking the non-darunavir containing regimens will also be described.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione PENTA Onlus

Networks

EPPICC

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Carlo Giaquinto

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/03/2011

Study start date

Actual: 01/12/2013

Date of final study report

Planned: 30/09/2017

Actual: 18/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag International NV

Study protocol

[TMC114-EPPICC growth CTP\[1\].pdf](#) (376.13 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 topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Describe characteristics of HIV-infected children ever received a darunavir (DRV) -containing regimen, describe the change in height for age z-score (HAZ) pre- and post-DRV exposure. Compare the change in HAZ in those taking a DRV-containing regimen to those taking other non-DRV containing regimens.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Population studied

Short description of the study population

All HIV-infected children aged <18 years at initiation of cART with at least one height measurement at the start of cART and at least one measurement ≥ 1 year subsequently.

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

175

Study design details

Data analysis plan

Standard descriptive statistics to summarize demographic, clinical and drug utilization data for children taking DRV-containing and non-DRV-containing regimens within the EPPICC data set. Data on height will be transformed to height for age z-score (HAZ) based on the WHO Child Growth Standards and WHO Reference 2007. Comparability of groups initiating DRV-containing and non-DRV containing cART will be assessed using propensity scores. Providing sufficient overlap between the 2 groups, change in HAZ score will be compared

using multilevel regression models to take account of the hierarchical structure of the data (repeated HAZ measurements for each child, and children within different cohorts). A fractional polynomial will be used to model change in HAZ over time, adjusting for baseline covariates related to demographic, HIV disease, treatment history and anthropometric characteristics.

Documents

Study results

[TMC114_EPPICC_Darunavir_Growth_Final_Study_Report_2017_08_18.pdf](#) (4.15 MB)

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

Retrospective collection of patient-level data from observational cohort studies. Data include demographics (date of birth, country of birth, sex, mode of infection, ethnicity, hepatitis B/C co-infection), weights and heights at every clinic visit, complete ART treatment and dosing history, CDC disease stage, complete CD4s and viral loads. Where available, data on Tanner stage will also be collected

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