Prevalence of primary and secondary arterial hypertension in children and treatment with angiotensin II receptor blockers

First published: 21/06/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS104305

Study ID

104306

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

A descriptive study of the yearly prevalence of primary and secondary arterial hypertension in children and their treatment with angiotensin II receptor blockers

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 11/03/2022

Actual: 11/03/2022

Study start date
Planned: 11/03/2022

Actual: 11/03/2022

Date of final study report
Planned: 12/04/2022

Actual: 11/04/2022

Sources of funding

- EMA

Study protocol

Analysis Plan_Arterial hypertension and ARBs use in children - For publication_CLEAN.pdf (485.51 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objective of this study was to estimate the number of children with arterial hypertension by age group and gender, and describe risk factors for primary hypertension or potential causes of secondary hypertension, estimate the yearly prevalence of arterial hypertension in children and the yearly proportion

of children with arterial hypertension treated with ARBs by age group.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09D) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

Medical condition to be studied

Hypertension

Population studied

Short description of the study population

The study involved children aged 2-17 years with arterial hypertension from January 2016 to June 2021 in the IQIVA™ Disease Analyzer France and Germany databases, and from January 1990 to May 2021 for IMRD (UK), including those registered or treated by general practioners and children treated by paediatricians in Germany, as pediatricians are part of primary care.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Patients with arterial hypertension

Estimated number of subjects

14.000

Study design details

Data analysis plan

A descriptive analysis of risk factors for arterial hypertension was carried in children 2-17 years with arterial hypertension during the study period (2016-2019). The yearly prevalence of arterial hypertension during the study period was calculated in children 2-17 years that were observable for at least one day during the year. Children with arterial hypertension during the year or with a history of arterial hypertension were included in the numerator, and the prevalence was the number of children in the numerator per 100,000 children observed for a year. Among yearly prevalent children with arterial hypertension, the proportion of children that also had a prescription for an ARB during the year was calculated. the yearly total number of children 2-17 years with an ARB prescription was identified, and among these children the proportion of children with a diagnosis of arterial hypertension during the year or earlier was calculated.

Documents

Study results

Arterial hypertension and ARBs use in children - Study report_for publication_CLEAN.pdf (741.1 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 source(s)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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