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

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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)

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Contact details

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Study contact

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Primary lead investigator

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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?

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

14000

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 stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No