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

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104306

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 institution and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024
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Institution

Contact details

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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 data collection

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

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

Data sources

Data source(s)
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