

# 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

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### Study ID

104306

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 United Kingdom

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## 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

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## Study status

Finalised

## Research institutions and networks

### Institutions

[European Medicines Agency \(EMA\)](#)

**First published:** 01/02/2024

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**Institution**

## Contact details

### Study institution contact

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**Study contact**

[Karin.Hedenmalm@ema.europa.eu](mailto:Karin.Hedenmalm@ema.europa.eu)

### Primary lead investigator

Karin Hedenmalm

## Study timelines

### **Date when funding contract was signed**

Planned: 11/03/2022

Actual: 11/03/2022

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### **Study start date**

Planned: 11/03/2022

Actual: 11/03/2022

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### **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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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### **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 practitioners and children treated by paediatricians in Germany, as paediatricians are part of primary care.

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### **Age groups**

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

Other

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### **Special population of interest, other**

Patients with arterial hypertension

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### **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)

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## 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](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No