

# DARWIN EU® - RR Childhood hypertension and sartans prescribing in children

**First published:** 18/08/2025

**Last updated:** 19/03/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000714

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### Study ID

1000000714

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### DARWIN EU® study


Yes

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### Study countries

-  Croatia
-  Denmark
-  Finland
-  France
-  Germany
-  Hungary

 Netherlands

 Norway

 Spain

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## **Study description**

Childhood hypertension (CHT), defined as elevated blood pressure in children and adolescents, is a significant health concern due to its association with organ damage during childhood, increased risk of hypertension as a young adult, and serious adverse cardiovascular outcomes in adulthood. CHT can be classified into two main categories. Primary hypertension refers to cases without an identifiable underlying cause, while hypertension that results from a specific underlying, potentially reversible cause, is classified as secondary hypertension. Secondary hypertension is frequently caused by coarctation of the aorta or renal diseases but can also be triggered by other causes.(4) Among the pharmacological options available for managing CHT, angiotensin receptor blockers, commonly referred to as sartans, are among the recommend first-line antihypertensive treatments. However, real-world data on prevalence of CHT and the prescribing patterns of sartans, and other antihypertensive medications in the paediatric populations remain limited. This study aims to generate real-world evidence on the epidemiology of CHT and prescribing patterns of sartans, and other antihypertensive medication among individuals with CHT across Europe to support regulatory decision-making and inform clinical practice.

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## **Study status**

Finalised

## Research institutions and networks

### Institutions

# Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

 Netherlands

**First published:** 03/11/2022

**Last updated:** 02/05/2024


**Institution**

**Educational Institution**


**ENCePP partner**


## Networks


### Data Analysis and Real World Interrogation Network (DARWIN EU®)


 Belgium

 Croatia

 Denmark


 Estonia

 Finland


 France


 Germany


 Greece


 Hungary


 Italy


 Netherlands

 Norway

 Portugal

 Spain

 Sweden

 United Kingdom

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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

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Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Ellen Gerritsen

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 16/06/2025

Actual: 16/06/2025

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### Study start date

Planned: 11/07/2025

Actual: 11/07/2025

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### **Date of final study report**

Planned: 30/01/2026

Actual: 21/01/2026

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P4-C1-015\\_DUS Sartans in children\\_V2.0.pdf](#) (755.53 KB)

[DARWIN EU\\_Protocol\\_P4-C2-012\\_DUS Sartans in children\\_V2.0.pdf](#) (772.02 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:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology  
Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

A cohort study will be conducted using routinely collected health data.

**Main study objective:**

The aim of this study is to assess the prevalence of childhood hypertension and of sartans and other antihypertensive medication prescribing among patients with childhood hypertension in European countries.

The specific objectives of this study are:

1. To estimate the annual prevalence of childhood hypertension (CHT) in the paediatric population. Results will be stratified by age group (children vs. adolescents), sex, and type of hypertension (primary vs. secondary).
2. To estimate the annual prevalence of sartans and other antihypertensive medication prescribing in patients with childhood hypertension (CHT). Results will be stratified by drug class, age group (children vs. adolescents), sex, and type of hypertension (primary vs. secondary).

## Study Design

## **Non-interventional study design**

Cohort

# Study drug and medical condition

## **Medicinal product name, other**

Sartans drugs classes with corresponding WHO ATC code (classified at 4th level)

Antihypertensive drug classes with corresponding WHO ATC code (classified at 2nd level)

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## **Anatomical Therapeutic Chemical (ATC) code**

(C09CA) Angiotensin II receptor blockers (ARBs), plain

Angiotensin II receptor blockers (ARBs), plain

(C09DA) Angiotensin II receptor blockers (ARBs) and diuretics

Angiotensin II receptor blockers (ARBs) and diuretics

(C09DB) Angiotensin II receptor blockers (ARBs) and calcium channel blockers

Angiotensin II receptor blockers (ARBs) and calcium channel blockers

(C09DX) Angiotensin II receptor blockers (ARBs), other combinations

Angiotensin II receptor blockers (ARBs), other combinations

(C03) DIURETICS

DIURETICS

(C07) BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

(C08) CALCIUM CHANNEL BLOCKERS

CALCIUM CHANNEL BLOCKERS

(C09) AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

### **Medical condition to be studied**

Hypertension

## Population studied

### **Short description of the study population**

For prevalence calculations of CHT (objective 1), the study population will include all individuals who are 18 years or younger and registered in the data source between the 1st of January 2015 and 31st of December 2024 (or the latest data available of the respective data source).

For prevalence calculations of prescribing of sartans and other antihypertensive medications in patients with CHT (objective 2), the study population will include all individuals registered in the data source with a condition occurrence of CHT, defined as a SNOMED diagnostic code for hypertension, in individuals who are 18 years and younger, between the 1st of January 2015 and 31st of December 2024 (or the latest data available of the respective data source).

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### **Age groups**

- **Paediatric Population (< 18 years)**

- Neonate
  - Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

## Study design details

## Outcomes

### Objective 1:

The outcome for this objective is as follows:

- Occurrence of CHT, defined as a recorded SNOMED diagnostic code for hypertension in individuals aged 18 years or younger.

### Objective 2:

The outcome for this objective is as follows:

- Prescribing of pre-specified antihypertensive medication among individuals with CHT, defined as a recorded RxNorm prescription of pre-specified antihypertensive medication in individuals diagnosed with hypertension and aged 18 years or younger.
  - Sartans (WHO ATC codes C09CA, C09DA, C09DB, C09DX) will be assessed per drug class at WHO ATC level 4.
  - Other pre-specified antihypertensive medication (WHO ATC codes C03, C07, C08, C09) will be assessed per drug class at WHO ATC level 2.

## Documents

### Study report

[DARWIN EU\\_Report\\_P4-C1-015\\_P4-C2-012\\_DUS sartans childhood hypertension\\_V4.0.pdf](#) (4.61 MB)

[Shiny App](#)

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)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Clinical Data Warehouse of the Bordeaux University Hospital

Integrated Primary Care Information (IPCI)

TaUH patient cohort (FinOMOP)

InGef Research Database

Semmelweis University Clinical Data

Norwegian Linked Health registry at University of Oslo

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

The Information System for Research in Primary Care (SIDIAP)

## Use of a Common Data Model (CDM)

### CDM mapping

Yes

### CDM Mappings

**CDM name**

OMOP

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**CDM website**

<https://www.ohdsi.org/Data-standardization/>

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**CDM version**

<https://ohdsi.github.io/CommonDataModel/index.html>

## 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