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

First published: 18/08/2025

Last updated: 06/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000714

Study ID

1000000714

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary

- [ ] Netherlands
- [ ] Norway
- [ ] Spain

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.

Study status

Ongoing

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

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Primary lead investigator

Ellen Gerritsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/06/2025

Actual: 16/06/2025

Study start date

Planned: 11/07/2025

Actual: 11/07/2025

Date of final study report
Planned: 30/01/2026

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

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

Name of medicine, other

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

• C09CA: Angiotensin II receptor blockers, plain
• C09DA: Angiotensin II receptor blockers and diuretics
• C09DB: Angiotensin II receptor blockers and calcium channel blockers
• C09DX: Angiotensin II receptor blockers, other combinations

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

• C03: Diuretics
• C07: Beta blocking agents
• C08: Calcium channel blockers
• C09: Agents acting on the renin-angiotensin system

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).

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)

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

CDM website

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

CDM version

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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No