# Prevalence of hypereosinophilic syndrome (HES) in the paediatric population in EU (Hypereosinophilic syndrome in children)

First published: 24/01/2022

**Last updated:** 24/01/2022





# Administrative details

**Study description** 

EU PAS number		
EUPAS45202		
Study ID		
45203		
DARWIN EU® study		
No		
Study countries		
France		
Germany		

HES is a constitutes a rare and heterogeneous group of disorders, defined as persistent and marked blood eosinophilia and/or tissue eosinophilia associated with a wide range of clinical manifestations reflecting eosinophil-induced tissue/organ damage 1. There is only limited information in the literature regarding the prevalence of this conditions in children and clarification of this would help inform the feasibility of current and future clinical trials. This study aims to calculate the yearly prevalence of hypereosinophilic syndrome in children 0-5 and 6-11 years of age in two European countries, France and Germany.

#### **Study status**

**Finalised** 

## Research institutions and networks

## Institutions

# European Medicines Agency (EMA)

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

#### **Study institution contact**

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Study contact

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## **Primary lead investigator**

## Hedenmalm Karin

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 29/11/2021

Actual: 29/11/2021

#### Study start date

Planned: 01/12/2021

Actual: 01/12/2021

#### Data analysis start date

Planned: 05/12/2021

Actual: 05/12/2021

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

Planned: 10/12/2021

Actual: 10/12/2021

# Sources of funding

EMA

# Regulatory

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
Study type:
Non-interventional study
Scope of the study:
Disease epidemiology
Data collection methods:
Secondary use of data
Main study objective:
The objective of this study was to calculate the prevalence of HES in paediatric population.

Was the study required by a regulatory body?

# Study Design

#### Non-interventional study design

Other

## Non-interventional study design, other

Descriptive study

# Study drug and medical condition

#### Medical condition to be studied

Hypereosinophilic syndrome

# Population studied

#### Short description of the study population

Children 0-11 years of age with possible HES who were identified between January 2010 and June 2021.

#### Age groups

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

### **Estimated number of subjects**

500000

# Study design details

#### **Outcomes**

#### Data analysis plan

Patients were considered observable between their first and their last visit to the practice. Age was calculated for each year during the study period. All children aged 0-11 years with at least one day of observability during the year were included in the yearly prevalence calculation. The age groups 0-5 years and 6-11 years were considered separately. The number of patients with possible HES, and of patients with confirmed HES was provided, cumulatively and per year. Children 0-11 years diagnosed with HES either during the year or earlier were considered to have HES during the year. The number of children that were diagnosed with HES during the year were provided separately. The number of children with HES was expressed as a fraction per million children observed during the year.

## **Documents**

#### Study results

Updated HES Report - Confidential info edited.pdf (479.85 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)

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

## **Data sources (types)**

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**