

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

**First published:** 24/01/2022

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Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/45203>

### EU PAS number

EUPAS45202

### Study ID

45203

### DARWIN EU® study

No

### Study countries

France  
Germany

### Study description

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 institution and networks

## Institutions

### European Medicines Agency (EMA)

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Institution

## Contact details

### Study institution contact

Hedenmalm Karin

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

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

Planned:

10/12/2021

Actual:

10/12/2021

## Sources of funding

- EMA

## 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary data collection

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**Main study objective:**

The objective of this study was to calculate the prevalence of HES in paediatric population.

## Study Design

**Non-interventional study design**

Other

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**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.

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**Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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**Estimated number of subjects**

500000

## Study design details

**Outcomes**

Hypereosinophilic syndrome

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## 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\(479.85 KB\)](#)

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## Data management

### Data sources

#### Data source(s)

Disease Analyzer - OMOP  
Disease Analyzer Germany

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#### Data sources (types)

[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