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

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 institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

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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

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

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.

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

Hypereosinophilic syndrome

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

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

No