Observational study to quantify in real life the contribution of SINGULAIR ® 4mg in children aged from 6 to 24 months (NA)

First published: 07/06/2016

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13721

Study ID

19575

DARWIN EU® study

No

Study countries

France

Study description

SINGULAIR® 4mg is an additive treatment to inhaled corticosteroids in 6 month to 5 year children with mild to moderate persistent asthma, inadequately controlled by inhaled corticosteroids and in whom immediate and short-term beta 2 agonists, administered at the request, does not provide sufficient clinical asthma control. The French Economic Committee for Health Products (CEPS) asked MSD France laboratory "to establish an epidemiological study of children under 2 years old, with the primary objective to determine whether the introduction of SINGULAIR® in the therapeutic arsenal provides better control of mild to moderate persistent asthma, poorly controlled when real prescribing practice is in relation to existing recommendations".Based on the French national health insurance database (SNII-RAM) which contains healthcare reimbursement data of the French population, the objective of this study is to compare the support, following an exacerbation, of children aged from 6 to 24 months with persistent asthma, between the addition of SINGULAIR® 4mg and a reinforcement of inhaled corticosteroids, according to existing guidelines.

Study status

Finalised

Research institutions and networks

Institutions

PharmacoEpidemiology Unit (PELyon), Claude Bernard Lyon 1 University

France

First published: 27/04/2010

Last updated: 21/09/2016

Institution | Outdated | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

ERIC VAN GANSE

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/10/2011

Actual: 03/10/2011

Study start date

Planned: 21/12/2012

Actual: 21/12/2012

Data analysis start date

Planned: 02/05/2013

Actual: 02/05/2013

Date of final study report

Planned: 30/09/2013

Actual: 30/09/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD France

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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective was to assess the characteristics, medical management, andMedical Resources Utilization of recurrent wheezing infants identified from national claims data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Singulair

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Children under 2 years old with mild to moderate persistent asthma, poorly controlled when real prescribing practice.

Age groups

- Infants and toddlers (28 days – 23 months)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

115.500

Study design details

Outcomes

Number of exacerbations during follow-up periodTime to the 1st exacerbation, number of visits to GPnumber of visits to pneumologistother MRU associated to asthmanumber of dispensations of antibioticsnumber of dispensations other dispensations

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Data analysis plan

1. Descriptive analysis of quantitative and ordinal variables (number and frequency of each therapeutic scheme, with 95% IC).Descriptive analysis of qualitative variables (average, standard deviation, median, percentiles and lower and higher limits). Outliers identified by boxplots.2. Comparative analysis

after matching (infants under Singulair vs. infants under IC)

Documents

Study publications

Belhassen M, de Pouvourville G, Laforest L, Brouard J, de Blic J, Fauroux B, La...

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 sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown