Quality of asthma treatment in children and adolescents (QUAST)

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/31230

EU PAS number

EUPAS29076

Study ID

31230

DARWIN EU® study

No

Study countries

France

Study description

Asthma is the most common chronic child and adolescent disease with a prevalence that has increased significantly over the past 20 years worldwide as well as the use of antiasthmatic medications. Little is known about the short and long-term therapeutic management of asthmatic children. Pharmacological treatment aims durable asthma control but despite the existence of international recommendations for the proper use of antiasthma drugs and inhalation medical devices in this population, asthma control remains unacceptable for at least one-third of asthmatic children and adolescents. The aim of this study is to assess the prescribing patterns of antiasthma drugs and inhalation medical devices, oral corticosteroids and antibiotics in asthmatic children in primary care in France in order to identify deviations from recommendations.

Research institution and networks

Institutions



Contact details

Study institution contact

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Study contact

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Primary lead investigator

Florentia KAGUELIDOU

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

02/11/2016

Study start date

Planned: 01/01/2018

Actual:

11/05/2018

Date of final study report

Planned: 31/12/2020

Sources of funding

Other

More details on funding

ANSM

Regulatory

Was the study required by a regulatory body? No

Is the study required by a Risk Management Plan (RMP)? Not applicable

Methodological aspects

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The aim of this study is to assess the prescribing patterns of antiasthma drugs (ATC classe R03) and inhalation medical devices, oral corticosteroids and antibiotics in asthmatic children in primary care in France in order to identify deviations from recommendations.

Study Design

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
(H02AB) Glucocorticoids
(H02BX) Corticosteroids for systemic use, combinations
(J01) ANTIBACTERIALS FOR SYSTEMIC USE

Medical condition to be studied Asthma

Population studied

Age groups

Children (2 to < 12 years) Adolescents (12 to < 18 years)

Estimated number of subjects 140000

Study design details

Outcomes

- To describe the prescribing patterns of antiasthma drugs and inhalation medical devices, oral corticosteroids, antibiotics and vaccines in asthmatic children in primary care, and their evolution over time.- To quantify the number of prescriptions that do not comply with international recommendations. - To compare the use of antibiotics within 2 years of the diagnosis of persistent asthma between matched asthmatic and non-asthmatic children and adolescents.- To describe the use of influenza vaccination in asthmatic children and adolescents.

Data analysis plan

A retrospective cohort study between January 2011 and December 2017 using the EGB database, a 1/97th sample of the French national healthcare insurance system. Claims data for all individuals aged from 5 to 18 years old will be analysed. Exposure of interest will be identified via ATC codes. Prevalence and incidence rate will be calculated. Volume of use will be assessed as total number of prescriptions dispensed and DU90%. Users will be classified as occasional if they are dispensed antiasthmatic drugs only once during the year, low users if they are dispensed twice and high users if they are dispensed three or more times in a 12-months period. Severity of asthma will be assessed according to the

number of antiasthmatic drugs classes prescribed in a 12-months period. All analyses will be stratified by year, age(5-11, 12-18 years) and gender. Adherence to recommendations will be assessed considering specific drugs dispensed and dosage, age, asthma severity, inhaled device prescription.

Data management

Data sources

Data sources (types)

Administrative data (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

No