

Study of the impact of non-compliance with GINA recommendations on the care consumption of adult asthmatic patient

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/15436>

EU PAS number

EUPAS5309

Study ID

15436

DARWIN EU® study

No

Study countries

France

Study description

Asthma is a chronic disease that has major implications not only in terms of morbidity and mortality or of deterioration in the quality of life for patients, but also in terms of costs associated with the disease. The management of persistent asthma (GINA 2, 3 and 4) is mainly based on the trigger eviction and on drug therapy. In current medical practice, asthma remains generally under-diagnosed, under-treated and poorly controlled yet. Based on the French national health insurance database (EGB), which contains healthcare reimbursement data of 1/97 of the French population, this study aims to better understand the impact of non-compliance with GINA therapeutic recommendations on healthcare use

and on absenteeism of persistent asthmatic patients. It also identifies the characteristics of patients whose care is not in accordance with these recommendations and tests the economic impact of medical nomadism on the management of asthma in 2007 and 2008.

Study status

Finalised

Research institution and networks

Institutions

Université Claude Bernard Lyon 1

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Institution

Contact details

Study institution contact

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Primary lead investigator

Eric VAN GANSE

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

30/06/2009

Study start date

Actual:

30/10/2009

Date of final study report

Actual:

31/03/2011

Sources of funding

- Other

More details on funding

CNAMTS

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

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary data collection

Main study objective:

This study aims to better understand the impact of non-compliance with GINA therapeutic recommendations on healthcare use and on absenteeism of persistent asthmatic patients. It also identifies the characteristics of patients whose care is not in accordance with these recommendations and tests the economic impact of medical nomadism on the

management of asthma in 2007 and 2008.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Persistent asthmatic patients.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

2000

Study design details

Outcomes

To study the frequency of non-compliance with GINA recommendations and its potential impact on health care consumption and absenteeism in asthmatic patients. To study and compare the characteristics of patients, their health care consumption and nomadism in 2007 and 2008.

Data analysis plan

A / Description of the general characteristics of the study population on 01/01/2007.B / Description of the components of the healthcare consumption and absenteeism in 2007 and 2008 for the entire population included.C / Study of the characteristics of the healthcare consumption and absenteeism of patients in 2007 and 2008 depending on the frequency of rescues CI in 2007.D / Study of the characteristics of the healthcare consumption and absenteeism in 2007 and 2008 patients who received BAILDA without CI in 2007.E / Study of the characteristics of the healthcare consumption and absenteeism in 2007 and in 2008 patients with high BAICDA rescues in 2007.

Data management

Data sources

Data source(s), other

EGB France

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