The Association between Long-Acting Beta-Agonists and Prescribing of Oral Steroids for Asthma Exacerbations

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Study Finalised

Administrative details

EU PAS number

EUPAS13490

Study ID

14260

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This cohort study aims to examine the comparative effectiveness of inhaled long-acting beta-agonist (LABA), inhaled corticosteroid (ICS), and ICS/LABA combinations. Patients older than 12 years with asthma diagnosis in the Clinical Practice Research Datalink were followed up to evaluate asthma-related morbidity measured by oral corticosteroid(OCS) initiation within 12 months of initiating LABAs, ICSs, or ICSs/LABAs. Asthma severity 12 months before drug initiation and during follow-up was adjusted as a time-varying variable via marginal structural models.

Study status

Finalised

Research institutions and networks

Institutions

Ayad Ali

Contact details

Study institution contact

Ayad Ali ayadali@ufl.edu

Study contact

ayadali@ufl.edu

Primary lead investigator

Ayad Ali

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/05/2010

Actual: 30/05/2010

Study start date
Planned: 01/07/2010

Actual: 01/07/2010

Date of final study report
Planned: 10/10/2012

Actual: 10/10/2012

Sources of funding

- Other

More details on funding

University of Florida College of Pharmacy Perry A. Foote Eminent Scholar Chair Fund

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

This study aimed to examine the association between inhaled LABA monotherapy, ICS monotherapy, and ICS/LABA combination therapy, and prescribing of short courses of oral corticosteroids for asthma exacerbations in individuals older than 12 years with asthma in the United Kingdom.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

FORMOTEROL

SALMETEROL

BECLOMETASONE

BUDESONIDE

CICLESONIDE

FLUTICASONE

MOMETASONE

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients older than 12 years with asthma diagnosis in the Clinical Practice Research Datalink (CPRD).

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

51.103

Study design details

Outcomes

Prescribing short courses of oral corticosteroids for asthma exacerbations.

Data analysis plan

Multi-category exposure marginal structural models and time-varying exposure Cox regression analyses will be applied.

Documents

Study results

2015_ValueHealth.pdf (1.33 MB)

Study publications

Ali AK, Hartzema AG, Winterstein AG, Segal R, Lu X, Hendeles L. Application of ...

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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