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

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### 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**

51103

### 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

### **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 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