Inhaler adherence and time to GINA step 5 therapy in a real-life moderate to severe asthma population

First published: 15/04/2019

Last updated: 09/01/2020

Study Finalised

Administrative details

EU PAS number

EUPAS28437

Study ID

33037

DARWIN EU® study

No

Study countries

Australia

Study description

According to the international GINA guidelines for asthma, step 5 therapy could result in either more expensive (i.e. IL-5, IgE biologicals) or less safe (i.e. oral corticosteroids OCS) asthma treatments compared to inhaled medication. Therefore, assessment of medication adherence is essential before initiating GINA step 5. The study aims to assess the rates and time to GINA step 5 therapy in asthma patients initiating inhaled corticosteroids and long-acting beta agonists in fixed dose combinations (ICS/LABA FDC), and assess the association between initial inhaler adherence and follow-up risk of stepping-up. Data from the 10% random sample of the Australian Pharmaceutical Benefits Scheme will be used.

Study status

Finalised

Research institutions and networks

Institutions

Monash University

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Job van Boven

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/12/2018

Actual: 02/01/2019

Study start date

Planned: 15/03/2019

Actual: 15/03/2019

Data analysis start date

Planned: 16/03/2019

Actual: 16/03/2019

Date of interim report, if expected

Planned: 16/04/2019

Actual: 16/12/2019

Date of final study report

Planned: 31/12/2019

Actual: 31/12/2019

Sources of funding

- Other

More details on funding

University Medical Center Groningen, Monash University

Study protocol

Statistical Analysis Plan_PBS_asthma_adherence_final_clean.pdf (536.6 KB)

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess the rates and time to GINA step 5 therapy in asthma patients initiating ICS/LABA in fixed dose combinations (ICS/LABA FDC) and assess the impact of different inhaler adherence trajectories.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AK06) salmeterol and fluticasone

salmeterol and fluticasone

(R03AK07) formoterol and budesonide

formoterol and budesonide

(R03AK07) formoterol and budesonide

formoterol and budesonide

(R03AK10) vilanterol and fluticasone furoate

vilanterol and fluticasone furoate

(R03AK11) formoterol and fluticasone

formoterol and fluticasone

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients initiating inhaled corticosteroids and long-acting beta agonists in fixed dose combinations (ICS/LABA FDC).

Inclusion criteria are:

1. New user with a dispensed prescription of an ICS/LABA FDC product (defined as no dispensings of ICS/LABA FDC during the preceding 1 year)
2. At least one year of follow-up data available after the index date
3. At least one more ICS/LABA FDC dispensing (excluding index ICS/LABA FDC prescription) within one year after prescription at index date
4. ≥ 12 years and <45 years old at index date
5. At least 2 other respiratory dispensings (not being ICS/LABA FDC or GINA step 5 treatments) in the year before index date (i.e. any dispensings of single short-acting beta agonists (R03AC02, R03AC03, R03AK04, R03CC02, R03CC03), short-acting muscarinic antagonists (R03BB01), inhaled corticosteroids (R03BA), cromones
(R03BC), xanthines (R03DA), or leukotriene antagonists (R03DC))

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

3500

Study design details

Outcomes

The primary outcome of this study is the percentage of patients on ICS/LABA FDC that received GINA step 5 treatment, defined as any dispense of either (1) low dose OCS, (2) biologicals: omalizumab, mepolizumab, benralizumab or (3) LAMA. Total number of GINA step 5 step-ups (combined, and per subgroup of OCS, biological or LAMA and adherence trajectory) over the complete follow-up. Other secondary outcome is the time to GINA step 5 treatment.

Data analysis plan

Patient characteristics will be described using descriptive statistics. Categorical variables will be described by frequencies and percentages. Continuous variables will be described using mean (± standard deviation SD) for normally distributed data or median and interquartile range (IQR) for skewed distributions. Adherence to ICS/LABA FDC will be calculated using group-based trajectory modeling (GBTM) over a 1-year period after the index date. Hazard ratios for time to GINA step 5 therapy and corresponding 95% confidence

intervals will be assessed using Cox proportional hazards models. Kaplan-Meier plots will be examined to check the fulfillment of proportional hazards assumption.

Documents

Study results

EUPAS28437_study_summary.pdf (86.06 KB)

Study publications

van Boven JF, Koponen M, Lalic S, George J, Bell JS, Hew M, Ilomaki J. Trajecto...

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

No