CRITIKAL Study

First published: 25/06/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27569

EU PAS number

EUPAS9651

Study ID

27569

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ France
- ☐ Italy
- ☐ Netherlands

- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

To assess the association between patient/treatment factors, including inhaler technique, lung function and comorbidities and asthma control in patients receiving fixed dose combination therapy (FDC), inhaled corticosteroids/long-acting beta agonists (ICS/LABA), ± short-acting beta2-agonist (SABA) therapy.A further aim will be to identify errors in inhalation technique that constitute 'critical errors' defined as those that have an adverse effect on asthma control.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

- [ ] United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

Study institution contact

David Price

Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/05/2010

Study start date

Planned: 01/05/2010

Actual: 01/08/2011

Date of final study report

Planned: 01/05/2016

Actual: 09/05/2018

Sources of funding

- Other

- Pharmaceutical company and other private sector

More details on funding

Mundiphama, Teva, Rirl

Study protocol

Critikal Study_Protocol_31032015_V5.4.pdf(1.39 MB)

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the associate between patient/treatment factors, including inhaler technique, lung function and comorbidities, in predicting asthma control in patients receiving fixed dose combination therapy (FDC), inhaled corticosteroids/long-acting beta agonists (ICS/LABA), ± short-acting beta2-agonist (SABA) therapy.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients having a current asthma diagnosis and not having diagnosed COPD.

Patients must meet the following inclusion criteria:

1. Aged 16+ years at the date of their iHARP review

2. Receiving current asthma therapy as FDC ICS/LABA:

o ≥1 prescriptions for FDC ICS/LABA in the year prior to review via: DPI or MDI with or without a spacer device

3. Completed asthma review during which full study-relevant data were recorded, meeting standards of IPCRG, Global Initiative for Asthma (GINA) guidelines and

Quality and Outcomes Framework (QOF) recommendations

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

5000

Study design details

Outcomes

The GINA based asthma control categories (“controlled”, “partly controlled”, “uncontrolled”) with be assign based on the answers to 4 questions that correspond to the questions in the GINA guideline from 2015. Namely:Daytime symptoms (more than twice/week), Any night waking due to asthma, Needed reliever inhaler (more than twice/week), Any limitation to day time activity, Similar to the analysis of the primary outcomes, numbers and percentages of patients will be cross-tabulated and compared across the categories of:• Asthma risk assessment (“Higher risk”, “Moderate risk”, “Lower risk”) • Adherence (both subjective and objective) with three categories (“Poor”, “Borderline”, ”Good”)

Data analysis plan

Summary statistics will be produced for all explanatory and outcome variables for all the patients and for patients using the different types of inhaler devices (Diskus, Turbuhaler, MDI and MDI with spacers). For variables measured on the interval or ratio scale, these will include: Sample size (n), Percentage non-missing, Mean (Standard Deviation), Median (Inter-quartile range (25th and 75th percentiles))For categorical variables, the summary statistics will include: Sample size (n), Count and percentage by category (distribution)Univariate ordinal regression analyses will be carried out to identify those explanatory variables that are predictive ($p < 0.05$) of outcomes. These will be considered as potential confounders when modelling the outcome variables.Muivariate analyses will be carried out to develop of model of the most important factors in asthma control

Data management

Data sources

Data source(s), other

iHARP dataset, OPCRD

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown