Characterising patients at risk of failed Diskus use in primary care

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Study Finalised

Administrative details

EU PAS number

EUPAS8019

Study ID

8020

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] France
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain

☐ Sweden

☐ United Kingdom

Study description

The aim of this study is to identify patient characteristics in a large sample of primary care patients that use a Diskus inhaler. The prevalence and factors associated with inhaler misuse will be investigated. In addition we aim to assess the relationship between inhalation technique and clinical outcomes. These results should assist physicians in evaluating the potential impact of the type of device prescribed to a patient.This study will answer the following questions:• Which serious errors in Diskus inhaler technique are most frequently made?• Are certain patient characteristics linked to incorrect inhaler technique for Diskus?• Are patient reported outcomes linked to incorrect inhaler technique for Diskus?• Does incorrect inhaler technique correlate to asthma risk assessment?In addition, the type and frequency of serious errors being performed when using Diskus will be analysed to better characterise patient errors and identify ways in which inhaler technique may be improved.

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/09/2013

Actual: 03/09/2013

Study start date

Planned: 01/06/2011

Actual: 01/06/2011

Data analysis start date

Planned: 10/10/2013

Actual: 14/10/2013

Date of interim report, if expected
Planned: 10/01/2014

Actual: 10/01/2014

Date of final study report
Planned: 19/03/2014

Actual: 24/11/2014

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Teva, RiRL

Study protocol

R01613 Characterising patients with serious errors using Diskus_ protocol for Encepp registration_241114.pdf (1.67 MB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Medical device

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Device utilisation study

Data collection methods:

Secondary use of data

Main study objective:

1. Define the serious errors commonly performed by patients with asthma using Diskus 2. Characterise patients who perform serious errors using Diskus and those that do not3. Examine patient reported outcomes with Diskus usageThe above objectives will enable the relationship between inhalation technique and clinical outcomes to be investigated.

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

Adults aged ≥ 18 years with current diagnosis of asthma (Step 3 or 4 of Global Initiative for Asthma [GINA] guidelines) and receiving current asthma therapy as fixed dose combination (FDC) inhalation corticosteroids (ICS) in combination with long-acting beta agonist (LABA) by using a Diskus device.
Patients should be prescribed Diskus for regular/preventer asthma therapy.

Age groups

- 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

623

Study design details

Data analysis plan

Patients will be separated into two groups: those performing serious error(s) and those not. Patient demographics and clinical characteristics analysed as follows:Summary statistics were produced for all variables, as a complete dataset and by error categories analysed. Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$.Univariable logistic regression models, with a dichotomous indicator variable for serious errors made (yes/no) as the dependent variable and each patient characteristic as an explanatory variable, were first used to identify characteristics associated with making serious errors. Demographic and clinical characteristics associated with making ≥1 serious errors in the univariable model ($P<0.05$) were entered into a multivariable model, which was stepwise reduced to produce a final list of non-collinear independently associated variables.

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), other

Optimum Patient Care (OPC) United Kingdom, Spanish Primary Care Respiratory Group GP network (GRAP). Spain, Woolcock Institue of Medical Research Australia, Lunger i Praksis Norway, Universitair Medisch Centrum Gronigen (UMCG) Netherlands

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