# Characterising patients at risk of failed Diskus use in primary care

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# 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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# Contact details

## **Study institution contact**

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Study contact

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## **Primary lead investigator**

**Emily Davis** 

**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  $\geq$  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≤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

## 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