A real-life historic study assessing metabolic and other adverse effects of small versus large particle inhaled corticosteroids in relation to their clinical benefit in obstructive lung disease

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/10959

EU PAS number
EUPAS8832

Study ID
10959

DARWIN EU® study
No

Study countries
United Kingdom

Study description
Aims to compare metabolic and other adverse effects of small (QVAR and Ciclesonide) vs. large particle (FP and Clenil) ICS in patients initiating and stepping-up their ICS therapy, and comparing results to appropriate control groups. The primary outcomes are:Diagnosis of pneumonia Diagnosis of pneumonia confirmed by chest x-ray or resulting in hospitalisation within one month of diagnosisFirst diagnosis of type 2 diabetes and/or prescription for anti-diabetic medication Progression of ongoing type 2 diabetes treatment to insulinChange in anti-diabetic medication Change in HbA1c valueChange in BMI

Study status
Finalised

Research institution 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
Jessica Martin
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
01/02/2013

Study start date
Actual:
01/11/2013

Data analysis start date
Actual:
03/02/2014

Date of final study report
Planned:

01/06/2015
Actual:
29/04/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

Regulatory

Was the study required by a regulatory body?
No

Methodological aspects

Study type

Study type list

Study topic:
Human medicinal product
Disease /health condition

Study type:
Non-interventional study

Scope of the study:
Other

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

Data collection methods:

Secondary data collection

Main study objective:
Compare for large particle vs small particle ICS:Diagnosis of pneumonia First diagnosis of type 2 diabetes and/or prescription for anti-diabetic medication Progression of ongoing type 2 diabetes treatment to insulinChange in anti-diabetic medication (e.g. type or dose prescribed) Change in HbA1c valueChange in BMI

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
FLUTICASONE PROPIONATE
CICLESONIDE
BECLOMETASONE DIPROPIONATE

Medical condition to be studied
Chronic obstructive pulmonary disease
Pneumonia
Diabetes mellitus

Population studied

Short description of the study population
Obstructive lung disease patients initiating and stepping-up their Inhaled corticosteroids (ICS) therapy.

Age groups
Children (2 to < 12 years)
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
Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects
10000

Study design details

Outcomes
Co-primary outcomes:(i) First diagnosis of diabetes and/or prescription for anti-diabetic medication (ii) Progression of ongoing diabetes treatment to insulin(iii) Change in HbA1c value(iv) Change in anti-diabetic medication (e.g. type or dose prescribed) (v) Change in BMI (vi) Diagnosis of pneumonia (vii) Exacerbation of obstructive lung disease

Data analysis plan
Treatment arms will be compared using (conditional) logistic regression, Poisson regression and Cox regression.

Data management

Data sources

Data source(s), other
Optimum Patient Care Research Database (OPCRD) United Kingdom

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