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 institutions and networks

Institutions

Research in Real Life

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Institution

Contact details

Study institution contact

David Price

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 use of data

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