

Effectiveness of prescribing similar vs dissimilar devices for COPD management (phase 1)

First published: 04/08/2015

Last updated: 22/02/2024

Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/10951>

EU PAS number

EUPAS10559

Study ID

10951

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Phase 1 of the study will involve a categorisation (based on required inhalation technique) and descriptive summary of commonly prescribed devices for COPD management. •List of therapies available and inhaler devices prescribed for COPD management in a UK patient population •Categorisation of inhaler devices based on similarities in required inhalation speed and strength for correct use (i.e. groups of similar devices) •Patterns of inhaler device prescriptions, focusing on co-prescriptions for similar and dissimilar devices

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

Arjun Jain

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

06/02/2015

Study start date

Actual:

11/03/2015

Data analysis start date

Actual:

25/03/2015

Date of interim report, if expected

Actual:

20/05/2015

Date of final study report

Planned:

21/08/2015

Actual:
14/08/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

Study protocol

[DASG study similar vs dissimilar devices COPD_Protocol_phase1.pdf](#)(853.66 KB)

[DASG study similar vs dissimilar devices COPD_Phase 1_Protocol.pdf](#)(842.81 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Methodological aspects

Study type

Study type list

Study topic:

Medical device

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary data collection

Main study objective:

•List of therapies available and inhaler devices prescribed for COPD management in a UK patient population •Categorisation of inhaler devices based on similarities in required inhalation speed and strength for correct use (i.e. groups of similar devices) •Patterns of inhaler device prescriptions, focusing on co-prescriptions for similar and dissimilar devices

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Chronic obstructive pulmonary disease patients aged \geq 40 years who have \geq 2 different inhaled treatments

Age groups

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

53817

Study design details

Data analysis plan

Phase 1 of the study will involve a categorisation (based on required inhalation technique) and descriptive summary of commonly prescribed devices for COPD management.

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