Effectiveness of prescribing similar vs dissimilar devices for COPD management (phase 2)

First published: 09/09/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10923

Study ID

26276

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Effectiveness of prescribing similar vs dissimilar devices for COPD management (phase 2):− Compare the effectiveness (in terms of moderate and severe exacerbation prevention) of prescribing inhaler devices with similar inhalation techniques vs prescribing devices with dissimilar inhalation techniques in patients with COPD − Assess therapy adherence in patients with COPD prescribed inhaler devices with similar inhalation techniques vs patients prescribed devices with dissimilar inhalation techniques

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/06/2015

Actual: 08/04/2016

Study start date

Planned: 28/08/2015

Actual: 28/08/2015

Data analysis start date

Planned: 14/09/2015

Date of interim report, if expected

Planned: 25/01/2016

Date of final study report

Planned: 08/02/2016

Actual: 08/04/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

Study protocol

DASG study similar vs dissimilar devices COPD Phase 2_Protocol_AJ.pdf (848.37 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Medical device

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

-Compare the effectiveness (in terms of moderate and severe exacerbation prevention) of prescribing inhaler devices with similar inhalation techniques vs prescribing devices with dissimilar inhalation techniques in patients with COPD −Assess therapy adherence in patients with COPD prescribed inhaler devices with similar inhalation techni

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients with Quality and Outcomes Framework (QOF) coded diagnosis for COPD ever recorded; aged ≥ 40 years at prescription date; ≥ 2 years of continuous practice data; ≥ 1 prescription for SABA, SAMA, LABA or LAMA as monotherapy or combinations (+/- ICS) via a single device or similar devices, prior to the prescription date; ≥ 1 prescription for baseline device(s) and additional COPD therapy (LABA, LAMA, ICS or their combinations) via a separate inhaler device in the outcome period (including that at prescription date).

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

Outcomes

•Moderate and severe COPD exacerbation rate (sensitivity definition), •Short-acting beta2agonist (SABA) use•Adherence to COPD therapy

Data analysis plan

Phase 2 of the study will investigate the effectiveness of comparable vs. non-comparable devices (as categorised in phase 1) in terms of excaerbation rate, SABA use and adherence to COPD therapy.

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 Research Database (OPCRD)

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

Unknown