

# 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

### PURI

<https://redirect.ema.europa.eu/resource/26276>

### 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

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## 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

David Price

Study contact

[dprice@rirl.org](mailto:dprice@rirl.org)

## Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 18/06/2015

Actual: 08/04/2016

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### Study start date

Planned: 28/08/2015

Actual: 28/08/2015

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### Data analysis start date

Planned: 14/09/2015

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### Date of interim report, if expected

Planned: 25/01/2016

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### 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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  $\geq 40$  years at prescription date;  $\geq 2$  years of continuous practice data;  $\geq 1$  prescription for SABA, SAMA, LABA or LAMA as monotherapy or combinations (+/- ICS) via a single device or similar devices, prior to the prescription date;  $\geq 1$  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).

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## Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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## Special population of interest

Other

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## Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

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## 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

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## 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

### Data sources

#### Data source(s), other

Optimum Patient Care Research Database (OPCRD)

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#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

#### Check conformance

Unknown

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#### Check completeness

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown