# Describing inhaler errors when mixing various inhaler types on inhaler technique in Chronic Obstructive Pulmonary Disease (COPD): MISMATCH study

**First published:** 05/09/2022

**Last updated:** 17/01/2023

Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/50616

**EU PAS number**

EUPAS48776

**Study ID**

50616

**DARWIN EU® study**

No

**Study countries**

☐ Netherlands

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**Study description**

Background: Inhaled drug therapy is the cornerstone of COPD treatment. However, correct use of inhaler devices can be challenging. Incorrect use may affect drug delivery to the lungs and consequently therapy effectiveness. There is some evidence that handling errors will occur more frequently when a patient uses a mixture of inhalers that require very different techniques, such as a dry powder inhaler (DPI) together with a pressurised metered dose inhaler (pMDI), which is common in treatment of COPD. This study hypothesises that patients using a mixture of a DPI and a pMDI will make more and different types of inhaler technique errors, which are otherwise not recognised or accounted for in inhaler technique checklists, than patients using a DPI only. Some of these errors may lead to poorer outcomes in patients with COPD. The study will compare the nature and frequency of inhaler technique errors, by describing all errors observed rather than using pre-determined checklists, between two groups of patients with COPD: 1. Patients using a combination of a DPI and a pMDI (“Mixed-devices group”) 2. Patients using a single DPI (“DPI only group”) In addition, the study will explore to which extent specific inhaler technique errors can explain potential differences in COPD health status and/or exacerbation rate between both groups. Study design: Cross-sectional observational study reassessing the recorded videos of DPI inhaler technique obtained from participants of the PIFotal study. All types of errors, including actions that should be part of the pMDI technique, will be assessed. Study population: Patients (age ≥40 years) who received COPD maintenance therapy through a DPI in the last 3 months prior to inclusion in the PIFotal study. Data source: Participants of the PIFotal study from the Netherlands, Poland, Greece, Portugal and Spain. Sample size: 292 patients in the “Mixed-devices group” will be matched o a patient using the same DPI device only

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

### General Practitioners Research Institute (GPRI)

Netherlands

**First published:** 31/08/2022

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

## Contact details

**Study institution contact**

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**Primary lead investigator**

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**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 01/07/2022

Actual: 11/07/2022

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**Study start date**
Planned: 01/08/2022

Actual: 01/09/2022

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**Data analysis start date**
Planned: 12/10/2022

Actual: 15/10/2022

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**Date of final study report**
Planned: 15/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Chiesi Pharmaceuticals BV, the Netherlands

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Methodological aspects

## Study type

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

To compare the nature and frequency of inhaler technique errors, by describing all errors observed rather than using pre-determined checklists, between two groups of patients with COPD: 1. Patients using a combination of a DPI and a pMDI (“Mixed-devices group”) 2. Patients using a single DPI (“DPI only group”)

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

**Age groups**

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)

**Estimated number of subjects**

584

# Study design details

**Outcomes**

Type of inhaler technique error, COPD health status, measured as the Clinical COPD Questionnaire (CCQ) score and COPD Assessment Test (CAT) score

Number of COPD exacerbations in the last year

**Data analysis plan**

Distributions of inhaler technique errors (numbers and percentages) will be described for the total population and will be compared, and differences statistically tested, between two groups of patients: 1. Patients using a combination of a DPI and a pMDI (“Mixed-devices group”) 2. Patients using a single DPI (“DPI only group”) Balanced matching on the type of DPI-device will be used to control potential confounding of the association between the use of mixed-devices and occurrence of inhaler errors by device-type. Mixed effects logistic regression models will be used to adjust the associations between errors occurrence and the group for other potential confounders. Effect sizes will be expressed as Odds Ratios with 95% confidence intervals.

# Data management

# Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Data collected within the framework of the PIFotal study will be used. Reference: Leving, M. et al. Impact of PIF, Inhalation Technique and Medication Adherence on Health Status and Exacerbations in COPD: Protocol of a Real-World Observational Study (PIFotal COPD Study). Pulmonary Therapy 7, 591 (2021).

## 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