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

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## Administrative details

EU PAS number	
EUPAS48776	
Study ID	
50616	
DARWIN FUE stade	
DARWIN EU® study	
No	
Study countries	
Netherlands	

**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

#### **Study status**

Ongoing

### Research institutions and networks

### Institutions

General Practitioners Research Institute (GPRI)				
☐ Netherlands				
First published: 31/08/2022				
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Institution				

## Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Janwillem Kocks

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 01/07/2022

Actual: 11/07/2022

#### Study start date

Planned: 01/08/2022

Actual: 01/09/2022

#### Data analysis start date

Planned: 12/10/2022 Actual: 15/10/2022

#### **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

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

Not applicable

# Methodological aspects

Study type

Study type list

#### Study type:

Non-interventional study

#### 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

### **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 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**

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### **Check stability**

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No