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

EU PAS number

EUPAS48776

Study ID

50616

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

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Study status

Ongoing

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

Netherlands

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

Contact details

Study institution 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

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No