Real life assessment of chronic obstructive pulmonary disease Inhaler devices handling (INHALER)

First published: 04/11/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10753

Study ID

37451

DARWIN EU® study

No

Study countries

☐ France

Study description

The correct use of inhalation devices is essential to ensure the effectiveness of the treatment (Giraud and Roche, Eur Respir J 2002). We have shown in a large study published in 2003 that many patients make handling errors in real life (Molimard et al., J Aerosol Med 2003, Girodet et al., Therapie 2003). Since this study, new devices have been marketed in chronic obstructive pulmonary disease (COPD), including Breezehaler® and Respimat®. Interestingly, little is known regarding their real-life use. The aim of this study is to update data on device handling, including new devices, in a real-life setting in France. The primary objective is to evaluate real-life COPD patient handling of their usual inhaler (Breezhaler®, Diskus®, Handihaler®, Respimat®, Turbuhaler® or pressurized Metered Dose Inhaler) by general practitioners or pulmonologists.For this cross-sectional observational study, 1 000 GPs and 200 pulmonologists randomly selected from a geographically representative database, and who agree to participate in this study, will assess patient handling of their current inhaler. Five thousands patients will be requested to take a puff of their usual inhaler using their usual technique, which will be observed and rated by the physician. Patient characteristics, COPD history, and device use history, will be collected using a questionnaire. For each device (if a patient has several devices, each device will be studied) descriptive statistical analysis will be performed: the handling error rate will be estimated overall (handling errors will be classified as those independent or dependent of the inhalation system, and among the latter major/critical errors will be identified), as well as stratified according to patient characteristics, COPD history, device use history, and patient-reported treatment effect. Sensitivity analyses will be performed excluding patients having been trained within 3 months.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/03/2014

Study start date
Planned: 01/09/2014

Actual: 24/03/2015

Data analysis start date
Planned: 15/12/2015

Actual: 12/01/2016

Date of final study report
Planned: 30/09/2016

Actual: 30/09/2016

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

NOVARTIS PHARMA S.A.S., Public University: Université de Bordeaux

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

Handling of medical devices

Data collection methods:

Primary data collection

Main study objective:

The objective is to assess COPD patient handling with their usual inhaler (Breezhaler®, Handihaler®, Diskus®, pMDI, Respimat® or Turbuhaler®) in real-life by general practitioners or pulmonologists.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

General practitioners (GPs) and pulmonologists were recruited to participate in the study using paper mail or emails sent to all non-hospital-based pulmonologists and a random sample of GPs. They were asked to recruit patients above the age of 40 years, current or ex-smokers of ⩾10 pack-years, who had been using an inhaler device for more than 1 month for continuous treatment of COPD. Physicians asked their COPD patients using any of the six most common inhalers to come to the next visit with their own inhaler. They were requested to take a puff of their usual inhaler with their usual inhalation technique, which was observed and rated by the physician. Physicians were asked not to give any instructions before the test and to pay attention particularly to dose preparation and delivery.

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)

Special population of interest

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

5000

Study design details

Data analysis plan

Statistical analysis will provide a description of the selection of physicians and patients in the study, the characteristics of physicians, the characteristics of patients included the handling of each COPD inhaler device, the handling error rate of the COPD inhaler devices, the characteristics of patients presenting a handling error for each type of error.Statistical analysis will be performed after database lock using SAS® software. The descriptive analysis of qualitative and ordinal variables will be presented using the frequency and the proportion of each modality. Quantitative variables will be presented using the size, number of patients with missing data, the arithmetic mean, standard deviation, the first quartile, median, third quartile, and extreme values. Two-sided 95% confidence intervals (CI) will be assessed for the error rates. The CIs will be calculated using normal approximation, exact binomial or Poisson method according to the size of samples.

Documents

Study publications

Molimard M, Raherison C, Lignot S, Balestra A, Lamarque S, Chartier A, Droz-Per…

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

Prospective patient-based data collection

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