# Comparative study of COPD double therapy versus triple therapy: an EGB data analysis

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# Administrative details

EU PAS number
EUPAS26916
Study ID
26917
DARWIN EU® study
No
Study countries
France

### **Study description**

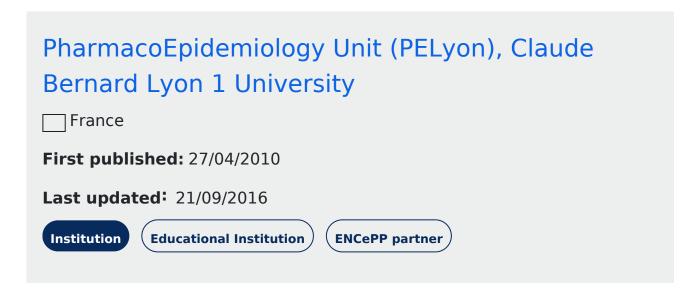
The primary objective of this study was to define the potential added value of triple therapy compared with double therapy (fixed or free combinations) in real use in COPD patients, in terms of exacerbations, healthcare consumption,

### **Study status**

Finalised

# Research institutions and networks

### Institutions



## Contact details

### **Study institution contact**

Faustine Dalon faustine.dalon@univ-lyon1.fr

Study contact

faustine.dalon@univ-lyon1.fr

### **Primary lead investigator**

**Eric VAN GANSE** 

Primary lead investigator

# Study timelines

### Date when funding contract was signed

Actual: 02/09/2016

### **Study start date**

Actual: 10/01/2017

### **Date of final study report**

Actual: 26/07/2017

# Sources of funding

Pharmaceutical company and other private sector

# More details on funding

Chiesi

# 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 topic:**

Disease /health condition

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

#### **Data collection methods:**

Secondary use of data

### Main study objective:

To compare dual and triple therapies after COPD hospitalizations, on exacerbations, healthcare resource use, costs and persistence.

# 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 hospitalized for Chronic obstructive pulmonary disease (COPD) and aged 45 and over.

#### Age groups

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**

3089

# Study design details

#### **Outcomes**

exacerbations, Hospitalization MedicationsVisits to physicians Medical acts

#### **Data analysis plan**

1:1 matching of the 2 cohortsMatching variables were the following:o Inclusion yearo Time between inclusion date and index date (+/- 5 days)o Incidence or not at the combination of dual or triple therapies.o Propensity scorePropensity score was calculated using a logistic regression model estimating the probability to be treated with a triple therapy, using the following confounding

factors calculated in the 12 months before index date: o Age at inclusion dateo Gendero CMU-Co Number of COPD treatmentso Number of exacerbationso Number of visits to a general practitionero Number of visits to a respiratory physiciano Presence/absence of the following comorbidities: cardiovascular diseases, depression, cancer and diabeteso Use or non-use of oxygen therapyo Use or non-use of non-invasive ventilationComparison using a Wilcoxon test for matched data

# Data management

### Data sources

### Data sources (types)

Administrative healthcare records (e.g., claims)

# 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**

Unknown