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

First published: 11/12/2018

Last updated: 01/04/2024

Study Finalised

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,

related costs and persistence.

Study status

Finalised

Research institutions and networks

Institutions

PharmacoEpidemiology Unit (PELyon), Claude Bernard Lyon 1 University

France

First published: 27/04/2010

Last updated: 21/09/2016

Institution | Outdated | Educational Institution | ENCePP partner

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

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)

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