Open Triple Therapy for Chronic Obstructive Pulmonary Disease: Patterns of Prescription, Exacerbations and Healthcare Costs From a Large Italian Claims Database

First published: 06/06/2024

Last updated: 06/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000156

Study ID

1000000156

DARWIN EU® study

No

Study countries

☐ Italy

Study description

An observational retrospective non-interventional cohort study of administrative halthcare data aimed to identify subjects with chronic obstructive pulmonary disease (COPD) treated with extemporaneous combination of inhaled corticosteroids (ICS)/long-actingβ2-agonist (LABA) and long-acting muscarinic antagonist (LAMA), namely open TT, and to describe the pharmacological strategy, the spirometry use, the exacerbations occurrence and the costs reimbursed by the Italian National Health System (SSN) in 1-year follow-up.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 01/10/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 08/01/2019

Study start date

Actual: 08/02/2019

Date of final study report

Actual: 08/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This research received the unconditional support of Glaxo Smith Kline, which did not have a role in the study design, in the collection, analysis and interpretation of data, in the writing of the report, and in the decision to submit the article for publication. The grant number is not available.

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

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Patients aged ≥45 supplied with at least 2 boxes of R03 drugs labelled for COPD during 2014 were identified. Subjects with asthma were excluded. Index date=the former date of filled prescription of ICS/LABA or of LAMA. One year before and one year after the index date were analysed.

Main study objective:
To describe the burden of patients aged 45 and older potentially eligible to the open TT in 2014, according to the authorized therapeutic indications, in terms of specific drugs supply, spirometry test performances, exacerbations occurrences, and of direct healthcare costs reimbursed by the SSN.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Medical condition to be studied
Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Italian population aged ≥45

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

Inpatient and oupatient

Summary results

In 2014, 10,352 patients (mean age 74 ± 9; males 66.0%) with COPD and treated with open TT were identified (prevalence 160.6 per 100,000 inhabitants aged ≥45). During the previous year, the 44.0% of this cohort was already treated with open TT, 7.0% did not received any drugs for obstructive airway diseases, 11.1% needed home oxygen therapy, and 28.7% experienced at least an exacerbation. In the follow-up year, the 37.5% of the cohort was found persistent to the open TT, 17.0% needed oxygen therapy, and the 30.9% underwent an exacerbation. Spirometry was performed on 45.7% of patients in the two previous years, while on 33.3% in the subsequent year. In the follow-up, on average, every patient of the cohort costed to the NHS €5,295: 48.2% for hospitalizations, 41.2% for drugs and 10.6% for outpatient services.

Documents

Study publications

Open triple therapy for chronic obstructive pulmonary disease: Patterns of pres…

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 source(s)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes