

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

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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 healthcare data aimed to identify subjects with chronic obstructive pulmonary disease (COPD) treated with extemporaneous combination of inhaled corticosteroids (ICS)/long-acting $\beta$ 2-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.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Fondazione ReS \(Ricerca e Salute\), CINECA partner](#)

☐ Italy

**First published:** 05/07/2017

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**Institution**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

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#### Study contact

[calabria@fondazioneres.it](mailto:calabria@fondazioneres.it)

#### Primary lead investigator

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#### Primary lead investigator

#### ORCID number:

0009-0001-3168-6856

## Study timelines

#### Date when funding contract was signed

Actual: 08/01/2019

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#### Study start date

Actual: 08/02/2019

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#### 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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Healthcare resource utilisation

## **Data collection methods:**

Secondary use of data

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## **Study design:**

Patients aged  $\geq 45$  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

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## **Medical condition to be studied**

Chronic obstructive pulmonary disease

# Population studied

## Short description of the study population

Italian population aged  $\geq 45$

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### Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly ( $\geq 65$  years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

## Study design details

### Setting

Inpatient and outpatient

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### Summary results

In 2014, 10,352 patients (mean age  $74 \pm 9$ ; males 66.0%) with COPD and treated with open TT were identified (prevalence 160.6 per 100,000 inhabitants aged  $\geq 45$ ). 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...](#)

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## 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

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### 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

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes