

# Preferences and consequences in therapy decision-making: tiotropium bromide plus olodaterol vs ICS-containing regimens in COPD patients in the Portuguese primary care setting: an observational, cross-sectional study (TIOLCOR Study)

**First published:** 16/06/2020

**Last updated:** 18/12/2025

Study

Cancelled

## Administrative details

### EU PAS number

EUPAS35841

---

### Study ID

48434

---

### DARWIN EU® study

No

---

### Study countries

Portugal

---

### Study description

What are the differences between patients prescribed a new maintenance treatment for COPD with tiotropium/olodaterol (TIO/OLO) or ICS-containing regimens in terms of sociodemographic, anthropometric and clinical characteristics? - STUDY WAS CANCELLED -

---

### Study status

Cancelled

## Research institutions and networks

### Institutions

**Boehringer Ingelheim**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Luis Pacheco [luis\\_2.pacheco@boehringer-ingelheim.com](mailto:luis_2.pacheco@boehringer-ingelheim.com)

**Study contact**

[luis\\_2.pacheco@boehringer-ingelheim.com](mailto:luis_2.pacheco@boehringer-ingelheim.com)

## Primary lead investigator

Luis Pacheco

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 30/10/2020

---

### Study start date

Planned: 30/06/2021

---

### Date of final study report

Planned: 30/06/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## 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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Evaluation of patient-reported outcomes

**Main study objective:**

To describe and compare the sociodemographic, anthropometric and clinical characteristics of COPD patients at the time of prescription of a new maintenance regimen with TIO/OLO or an ICS-containing regimen (free or fixed dose triple combination ICS/LABA/LAMA, LABA+ICS, LAMA+ICS, ICS monotherapy or other) in the Portuguese primary care setting.

## Study Design

**Non-interventional study design**

Cohort

Cross-sectional

## Study drug and medical condition

### **Medicinal product name**

SPIOLTO RESPIMAT

---

### **Anatomical Therapeutic Chemical (ATC) code**

(R01AD) Corticosteroids

Corticosteroids

---

### **Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

### **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)
- 

### **Estimated number of subjects**

300

## Study design details

## **Outcomes**

Demographic, anthropometric and clinical characteristics in the two study cohorts. Includes the number of patients for whom the new COPD treatment is in accordance with the GOLD 2019 Guideline recommendations, Patient symptomatology according to mMRC questionnaire and QoL according to EQ-5D-5L in the two study cohorts, Overall patient satisfaction with inhaler device according to a 5-point Likert scale and treatment satisfaction according to TSQM in the two study cohorts,

---

## **Data analysis plan**

All quantitative variables will be summarized using descriptive statistics. All qualitative variables will be summarized by absolute (n) and relative (%) frequencies. The statistical analysis will be performed through frequency tables for qualitative variables and tables with descriptive statistics for quantitative variables. A logistic regression will be used to explore the association between the dependent variable and independent variables of interest.

## 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)**

Electronic healthcare records (EHR)

## 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