# Assessment of physical functioning and handling of Spiolto® Respimat® in patients with chronic obstructive pulmonary disease (COPD) requiring long-acting dual bronchodilation in routine clinical practice (OTIVACTO)

**First published:** 13/12/2016

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS16629

**Study ID**

16933

**DARWIN EU® study**

No

**Study countries**

Spain

**Study description**

Reduced physical activity resulting in deconditioning and restricted physical functioning is a common constraint of patients with moderate to very severe COPD. Clinical studies investigating treatment with Spiolto® Respimat® and its single components have shown significant improvements in exercise capacity in patients with COPD.Real-world data on the effects of a fixed-dose combination (LABA+LAMA) therapy with tiotropium and olodaterol administered in a single device, in COPD patients who need treatment with two long-acting bronchodilators, is not available.)

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Boehringer Ingelheim

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

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Institution

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Ingelheim Boehringer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 13/02/2017

**Study start date**

Planned: 20/02/2017

**Data analysis start date**

Planned: 27/02/2017

**Date of final study report**

Planned: 30/06/2018

Actual: 02/08/2019

## 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

Other

**If ‘other’, further details on the scope of the study**

Measure changes in physical function

**Data collection methods:**

Primary data collection

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**Study design:**

Open-label observational study, including COPD patients in Spain receiving treatment with Spiolto® Respimat® for approximately 6 weeks, which is the average time between two medical consultations.

**Main study objective:**

The primary objective of the study is to measure changes in physical functioning - serving as a surrogate for physical activity and exercise capacity - in COPD patients being treated with Spiolto® Respimat® after approximately 6 weeks

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

SPIOLTO RESPIMAT

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**Study drug International non-proprietary name (INN) or common name**

TIOTROPIUM

OLODATEROL

**Anatomical Therapeutic Chemical (ATC) code**

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

**Medical condition to be studied**

Chronic obstructive pulmonary disease

# Population studied

**Age groups**

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

**Estimated number of subjects**

400

# Study design details

**Setting**

Patients ‘data from 57 Spanish sites was collected (primary care centres). Sites were selected to reflect routine clinical practice for COPD in order to ensure the representativeness of the population with COPD.

**Outcomes**

The primary objective is to evaluate the Physical Functioning based on Physical Functioning Questionnaire (PF-10)scores which consists of 10 questions evaluating the extent of experienced restrictions while conducting usual activities at visit 1 and at visit 2 with Spiolto® Respimat. The secondary objective is to evaluate the patient’s general condition (physician’s evaluation) at visit 1 (= baseline visit at the start of the study) and at visit 2 (= final visit approx. 6 weeks after visit 1), as well as patient satisfaction with Spiolto® Respimat® at visit 2.

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**Data analysis plan**

All patients who have received at least one dose of Spiolto® Respimat® will be included in the analysis, this is the treated set. All analyses will be performed on the treated set (as-treated analysis). If patients have missing values for an outcome, those patients will be excluded for that outcome’s analysis.The assessment will be carried out using SAS® software. The statistical characteristics presented in the end-of-text tables will be N / mean / SD / min / median / max for continuous variables. Tabulations of relative and absolute frequencies will be presented for categorical variables. Incidence rates and 95% CI will be given when appropriate

## Documents

**Study results**

1237-0058_Synopsis.pdf (237.8 KB)

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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 sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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