

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

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

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Ingelheim Boehringer MEDICABIITALIA@boehringer-
ingelheim.com

Study contact

MEDICABIITALIA@boehringer-ingelheim.com

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

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

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.

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)

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