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 RCV NIS)

First published: 18/03/2016

Last updated: 24/09/2026

Study Finalised

Administrative details

EU PAS number

EUPAS12864

Study ID

13460

DARWIN EU® study

No

Study countries

- Austria
- Bulgaria
- Croatia
- Czechia
- Hungary
- Israel
- Romania
- Russian Federation
- Slovakia
- Slovenia
- Switzerland

Study description

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.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.

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

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Primary lead investigator

Ingelheim Boehringer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/05/2015

Actual: 13/05/2015

Study start date

Planned: 19/04/2016

Actual: 11/04/2016

Date of final study report

Planned: 30/06/2016

Actual: 07/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim RCV GmbH & Co KG

Study protocol

1237-0044_clinical-trial-protocol.pdf (576.51 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

1237.44

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

Open-label observational study conducted in 6 countries, including COPD patients receiving treatment with Spiolto® Respimat®

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 drug and medical condition

Medicinal product name

SPIOLTO RESPIMAT

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

Short description of the study population

The following inclusion criteria were defined:

- Written informed consent prior to participation
- Female and male patients ≥ 40 years of age
- Patients diagnosed with COPD and requiring long-acting dual bronchodilation (LAMA + LABA) treatment according to approved Spiolto® Respimat® SmPC and COPD GOLD Strategy Document recommendation

Patients fulfilling any of the following exclusion criteria were excluded from study participation:

- Patients with contraindications according to Spiolto® Respimat® SmPC
- Patients who have been treated with a LABA/LAMA combination (free and fixed dose) in the previous 6 weeks
- Patients continuing LABA-ICS treatment should not be additionally treated with Spiolto® Respimat® in order to avoid a double dosing of long-acting beta-agonists
- Patients for whom further follow-up is not possible at the enrolling site during the planned study period of approx. 6 weeks
- Pregnancy and lactation
- Patients currently listed for lung transplantation
- Current participation in any clinical trial or any other non-interventional study

of a drug or device

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

7.000

Study design details

Setting

Between August 2016 and November 2017, 68 investigation sites in 6 countries (Belgium, Denmark, Luxembourg, the Netherlands, Portugal, Sweden), mainly office based pulmonologists and general practitioners,
participated in this NIS. The first patient was screened on 08 November 2016 and the last patient was
screened on 28 September 2017. Last patient out (LPO) was on 14 December 2017. In total, 132 patients of the planned 1200 patients were screened in 30 investigational sites. Patient enrolment was discontinued prematurely due to recruitment failure.

Outcomes

Primary outcomes:“Therapeutic success” at visit 2 (10-point increase in the PF-10 score between visit 1 and visit 2). Secondary outcomes:- Changes in the PF-10 score from visit 1 to visit 2- General condition of the patient, evaluated by

the physician (PGE score) at visit 1 and visit 2.- Patient satisfaction with Spiolto Respimat at visit 2.

Data analysis plan

For the primary outcome, the proportion of patients with therapeutic success will be presented together with the 95% confidence interval. The patient's general condition (PGE) at visit 1 and visit 2, mMRC at visit 1 and patient satisfaction at visit 2 are categorical variables so they will be analyzed as tabulations of frequencies. Change from visit 1 to visit 2 in the PF-10 score is a continuous outcome, so it will be analyzed with N / mean / SD / min / median / max.Subgroup analysis for maintenance naïve patients and the ones already treated at baseline with long acting bronchodilators (LABA only, LAMA only) or LABA + ICS will be performed for the primary outcome, if such subgroups include more than 20% of all patients.Subgroup analyses will be performed by GOLD spirometric classifications (2 vs. 3/4) and GOLD patient groups (B vs. C/D and B vs. C, vs. D) for the primary outcome and changes in PF-10 for the secondary outcome.

Documents

Study results

1237-0045_Synopsis.pdf (413.61 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