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: 15/05/2016





## 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
Ongoing
Research institutions and networks
Institutions
Boehringer Ingelheim

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### 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: 13/05/2015

Actual: 13/05/2015

#### Study start date

Planned: 19/04/2016 Actual: 11/04/2016

### Date of final study report

Planned: 30/06/2016

# Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim RCV GmbH & Co KG

## Regulatory

Was the study required by a regulatory body?

No

# Methodological aspects

# Study type

## Study type list

#### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

### 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

#### **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 (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**

7000

# Study design details

#### **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.

## 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