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 SPAIN)

First published: 09/06/2016

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Study | Finalised

Administrative details

EU PAS number

EUPAS13754

Study ID

32075

DARWIN EU® study

No

Study countries

Spain

Study description

This is a self-controlled study design enrolling consented COPD patients who will be treated with Spiolto® Respimat® according to the approved SmPC. Patients will be enrolled consecutively and will be followed over an observational period of approx. 6 weeks.

Study status

Finalised

Research institutions and networks

Institutions

Centro de Salud Francia

Multiple centres: 120 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Molina Jesus

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/02/2016

Actual: 16/06/2016

Study start date

Planned: 22/05/2017

Actual: 17/05/2017

Data analysis start date

Planned: 01/03/2019

Actual: 13/03/2019

Date of final study report

Planned: 27/09/2019

Actual: 04/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Spain

Study protocol

1237.58_CTP.pdf (559.57 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

1237.58

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The 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

Other

Non-interventional study design, other

Open-label observational study

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

Short description of the study population

COPD patients in Spain receiving treatment with Spiolto® Respimat® for approximately 6 weeks.

Inclusion criteria:

1. Written informed consent prior to participation

2. Female and male patients ≥ 40 years of age

3. Patients diagnosed with COPD and requiring long-acting dual bronchodilation (LAMA + LABA) treatment according to approved Spiolto® Respimat® SmPC and COPD GOLD guideline recommendation

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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)

Special population of interest

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

1.000

Study design details

Outcomes

Therapeutic success at visit 2 (10-point increase in the PF-10 score between visit 1 and 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

Baseline data will be described using a cross-sectional approach. Data from the longitudinal follow-up will be summarized descriptively. Due to the nature of this non-interventional study, there is no (confirmatory) hypothesis testing foreseen in a strict statistical sense.
Analyses are descriptive in nature and confidence intervals and p-values from statistical models are used for exploratory purposes.
No adjustments for multiple testing are made in the evaluation of statistical significance.
Consequently, significant differences may be observed by chance alone and p-values should be interpreted as exploratory and with caution.

Documents

Study results

OTIVACTO_Redacted Summary Results.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

Unknown