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: 18/03/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS12750

Study ID

29160

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Portugal
- [ ] Sweden

Study description

Assessment of physical functioning and handling of Spiolto®

Study status

Finalised

Research institutions and networks

Institutions

Cynthia de Roos-Verkleij

Multiple centres: 30 centers are involved in the study

Contact details

Study institution contact

Cynthia de Roos-Verkleij anja.mayer@boehringer-ingelheim.com

Study contact

anja.mayer@boehringer-ingelheim.com

Primary lead investigator

Cynthia de Roos-Verkleij

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2015

Actual: 01/09/2015

Study start date

Planned: 01/09/2016

Actual: 08/11/2016

Data analysis start date

Planned: 15/05/2018

Actual: 21/06/2018

Date of final study report

Planned: 22/12/2018

Actual: 07/12/2018

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Other

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

Influence of treatment on patient's physical functioning

Data collection methods:

Primary data collection

Main study objective:

To measure changes in physical functioning, a surrogate for physical activity and exercise capacity, in COPD patients on treatment with Spiolto® Respimat® in routine daily treatment after approximately 6 weeks

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Single group, open, non-randomised, observational

Study drug and medical condition

Medicinal product name, other

Spiolto Respimat

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients with chronic obstructive pulmonary disease (COPD) requiring long-acting dual bronchodilation in routine clinical practice who were on treatment with Spiolto® Respimat® in routine daily treatment after approximately 6 weeks.

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

1200

Study design details

Outcomes

Changes in physical functioning based on PF-10 scores, Patients' general condition using the Physician's Global Evaluation (PGE) scalePatients' satisfaction with Spiolto Respimat using a Patient Satisfaction Survey

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Data analysis plan

Descriptive statistics

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