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 (SPIRIT)

First published: 08/03/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/29782

EU PAS number

EUPAS12709

Study ID

29782

DARWIN EU® study

No

Study countries

☐ Germany

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. A 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 at the end of the study, 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

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Institution

Multiple centres: 650 centres are involved in the study

Contact details

Study institution contact

Andrea Marseille

Study contact

info@boehringer-ingelheim.com

Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/12/2015

Actual: 31/12/2015

Study start date

Planned: 29/02/2016

Actual: 11/02/2016

Date of final study report

Planned: 16/09/2017

Actual: 06/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharma GmbH&Co.KG

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

to measure changes in physical functioning -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

Anatomical Therapeutic Chemical (ATC) code

(R03AL) Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids

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Medical condition to be studied

Bronchial obstruction

Population studied

Short description of the study population

Chronic obstructive pulmonary disease (COPD) patients being treated with Spiolto® Respimat®.

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

2000

Study design details

Outcomes

Primary objective: Measure changes in physical functioning by PF-10 questionnaire in COPD patients treated with Spiolto Respimat after ca. 6 weeks in routine clinical practice, 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 at the end of the study, approx. 6 weeks after visit 1), as well as patient satisfaction with Spiolto® Respimat® at visit 2

Data analysis plan

Primary outcome: “therapeutic success” at visit 2.(10-point increase in the PF-10 score between visit 1 and visit 2).Secondary outcomes:Change 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.Subgroup analysis for maintenance naïve patients and the ones alreadytreated at baseline with long acting bronchodilators or LABA + ICSwill be performed for the primary outcome.Subgroup analyses will be performed by GOLD spirometricclassifications (2 vs. 3/4) and GOLD patient groups (B vs. C/D and Bvs. C vs. D) for the primary endpoint and changes in PF-10 for thesecondary outcome.

Data management

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