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: 28/09/2026

Study Finalised

Administrative details

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

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Study contact

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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

Study protocol

1237-0042_clinical-trial-protocol.pdf (582.24 KB)

1237-0042_protocol_redacted.pdf (582.24 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

1237.42

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Open-label prospective observational study according to §4, section 23 and §67, section 6 German Medicines Act: all included COPD patients received treatment with Spiolto® Respimat® for approximately 6 weeks, which is the average time between two medical consultations.

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

Medicinal product name

SPIOLTO RESPIMAT

Study drug International non-proprietary name (INN) or common name

OLODATEROL

Anatomical Therapeutic Chemical (ATC) code

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

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

2.000

Study design details

Setting

Between February 2016 and February 2017, 258 German investigational sites, mainly office-based pulmonologists and general practitioners, participated in NIS Spirit. The first patient was registered on 11 Feb 2016 and the last patient on 20 Feb 2017. Last patient last visit (LPLV) was on 06 Mar 2017.

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 already treated 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 the secondary outcome.

Documents

Study results

1237-0042_Synopsis.pdf (262.28 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