

AERIAL®: Changes in health and functional status in patients with COPD during therapy with Spiolto® Respimat®

First published: 27/04/2017

Last updated: 17/12/2025

Study

Finalised

Administrative details

EU PAS number

EUPAS18745

Study ID

34041

DARWIN EU® study

No

Study countries

Germany

Study description

The objective of this NIS is to measure changes in health status including functional status using CCQ scores in COPD patients receiving treatment with Spiolto® Respimat® after approximately 6 weeks in routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 144 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Adrian Gillissen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/10/2016

Actual: 18/10/2016

Study start date

Planned: 30/04/2017

Actual: 26/05/2017

Data analysis start date

Planned: 31/08/2018

Actual: 24/05/2019

Date of final study report

Planned: 31/12/2018

Actual: 18/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study protocol

[1237-0065_protocol_redacted.pdf](#) (1.05 MB)

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

Study design:

This was an open-label observational study according to §4, section 23 and §67, section 6 German Medicines Act. All included COPD patients have been receiving treatment with Spiolto® Respimat® for approximately 6 weeks, which is the average time between two medical consultations.

Main study objective:

The objective of this NIS is to measure changes in health status including functional status using CCQ scores in COPD patients receiving treatment with Spiolto® Respimat® after approximately 6 weeks in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SPIOLTO RESPIMAT

Medicinal product name, other

Spiolto Respimat

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

Chronic obstructive pulmonary disease (COPD) patients receiving treatment with Spiolto® Respimat® after approximately 6 weeks in routine clinical practice.

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

1300

Study design details

Setting

It was planned to collect data from approximately 1300 patients from approximately 400 sites in Germany in the period between Q2 2017 and Q2 2018. 1322 patients were registered at 114 sites with the first patient registered on March 31, 2017 and the last on November 10, 2018. Site selection was performed to reflect routine COPD care in Germany and to secure representativeness of the COPD population. Almost all sites were non-hospital (general practitioner and pulmonologists), one site was a pulmonology clinic. Patients were enrolled consecutively and followed over an observational period of approximately 6 weeks.

Outcomes

Primary objective: Assess proportion of patients achieving “therapeutic success” (= 0.4 point decrease in the CCQ score between baseline and approximately week 6), Secondary objectives: Assessment of changes in CCQ and CCQ-4, patient’s general condition at visit 1 (baseline and at visit 2 (approx. 6 weeks after visit 1), patient satisfaction with Spiolto® Respimat®, willingness to continue treatment with Spiolto® Respimat® at visit 2 as proxy for adherence

Data analysis plan

For the primary outcome, the proportion of patients with CCQ therapeutic success will be presented together with the 95% confidence interval. Patient’s general condition (PGE) at visit 1 and visit 2, patient satisfaction and willingness to continue treatment at visit 2 as categorical variables will be analyzed as tabulations of frequencies. Change from Visit 1 to Visit 2 in the CCQ and CCQ-4 score as continuous outcome 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 >20% of all patients. Subgroup analyses will be performed by GOLD spirometric classifications (2 vs. 3 vs. 4) and GOLD patient groups (B vs. C/D and B vs. C vs. D) for the primary outcome and changes in CCQ and CCQ-4 for the secondary outcome

Documents

Abstract of study report

[1237-0065_Synopsis.pdf](#) (226.2 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