Assessment of dyspnea and other symptoms as patient reported outcomes (PRO) in patients with chronic obstructive pulmonary disease (COPD), symptomatic on LABA/ICS maintenance therapy (now) treated with Spiolto® Respimat® (tiotropium/olodaterol) in comparison to open or fixed triple combination treatment in routine clinical practice (EVELUT)

First published: 20/05/2019

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS29784

Study ID

48046

DARWIN EU® study

No

Study countries

Germany

Study description

This prospective open-label observational study aims to analyze the comparative effectiveness of Spiolto® Respimat® in the new reusable inhaler vs any triple therapy in reducing dyspnea and symptom burden from each individual patient’s score difference between baseline and after approximately 12 weeks of treatment.

Study status

Finalised

Research institutions and networks

Institutions

Universitätsmedizin der Johannes Gutenberg

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Marseille Andrea andrea.marseille@boehringer-ingelheim.com

Study contact

andrea.marseille@boehringer-ingelheim.com

Primary lead investigator

Roland Buhl

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/11/2018

Actual: 21/11/2018

Study start date

Planned: 31/05/2019

Actual: 14/06/2019

Data analysis start date

Actual: 15/12/2021

Date of final study report

Planned: 30/09/2022

Actual: 19/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharma GmbH&Co.KG

Study protocol

1237-0087_protocol_redacted.pdf (1.09 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)

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

Open-label comparative multicentric cohort study

Main study objective:

The primary objective of this NIS is to investigate the changes in dyspnea (as measured via mMRC questionnaire) and symptom burden (as measured via CAT) in COPD patients dyspneic despite LABA/ICS maintenance treatment when switched to either Spiolto® Respimat® in the new reusable inhaler inhaler or to any triple therapy (free or fixed-dosed).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

Main inclusion criteria:

• ≥40 years old COPD patients symptomatic regarding dyspnea (mMRC Dyspnea score ≥1) AND regarding symptoms (CATTM Score ≥10) at the same time

• Patients on LABA/ICS maintenance therapy switched to Spiolto® Respimat® or a free/fixed triple combination of LAMA + LABA + ICS at Visit 1 at the discretion of the treating physician.

Main exclusion criteria:

• Patients with contraindications acc. to SmPC

• Acute exacerbation of COPD (within 4 weeks prior to Visit 1)

• Frequently exacerbating patients, i. e. patients with ≥2 moderate exacerbations within the last 12 months or ≥1 exacerbation leading to hospitalization within the last 12 months

• Acute respiratory failure (pH <7,35 and / or respiratory rate >30/min within 3 months prior to Visit 1)

• History or current diagnosis of asthma and asthma-COPD overlap, history of allergic rhinitis within the last 5 years

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)

Estimated number of subjects

900

Study design details

Outcomes

Two primary endpoints will be assessed:
Difference in mMRC (modified Medical Research Council) score at baseline and after end of observation (approx. 12 weeks of treatment, Visit 2) Difference in CATTM (COPD assessment test) score at baseline and after end of observation (approx.. 12 weeks of treatment, Visit 2),
• patients' general condition according to the Physician's Global Evaluation (PGE) score at baseline and end of the observation period of approximately 12 weeks,
• patient satisfaction with inhaler and therapy at end of observation period according to a seven-point ordinal scale (ranging from very dissatisfied to very satisfied)
• proportion of responders with mMRC ≥1 and with CAT ≥2

Data analysis plan

The estimation of the relative treatment effect concerning the primary outcomes is subject to potential confounding, therefore adjusted analyses are

required and will be performed. Multiple analytical approaches will be applied to allow an assessment of the sensitivity of the results to these approaches:

• Propensity score matching (primary analysis, requires data to be discarded from the analysis)

• Propensity score weighting (uses the complete data set)

• Multivariable regression modeling (uses the complete data set)

The relative treatment effect will be determined based on model coefficients (along with 95% confidence intervals) and statistical testing of these coefficients. Since the study is exploratory, no multiplicity adjustment is planned.

Documents

Study results

1237-0087_Synopsis.pdf (645.83 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