Changes in functional status in patients with Chronic Obstructive Pulmonary Disease (COPD) during therapy with Spiolto® Respimat® (ELLACTO)

First published: 26/10/2017

Last updated: 18/12/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS21422

Study ID

21423

DARWIN EU® study

No

Study countries

Greece

Study description

The aim of the NIS is to measure changes in functional statusserving as a surrogate for physical activity and exercise capacityin COPD patients receiving treatment with Spiolto ® Respimat®,at least for 6 weeks, embedded in a real life practice setting.A secondary objective is to evaluate the patient’s generalcondition (physician’s evaluation) from Visit 1 (baseline visitat the start of the study) to Visit 2 (final visit at the end of thestudy, approx. 6 weeks after Visit 1), as well as patientsatisfaction with Spiolto® Respimat® at Visit 2.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

Marousa Kouvela marousa.kouvela@boehringer-ingelheim.com

Study contact

marousa.kouvela@boehringer-ingelheim.com

Primary lead investigator

Marousa Kouvela

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2017

Study start date

Planned: 01/02/2018

Date of final study report

Planned: 29/03/2019

Actual: 07/01/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1237-0073_protocol_redacted.pdf (604.07 KB)

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:

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

This is a self-controlled non interventional study enrolling consented COPD patients who will be treated

with Spiolto® Respimat® according to approved SmPC. The Patients will be enrolled consecutively and
will be followed over an observational period of approx. 6 weeks.

Main study objective:
The aim of the NIS is to measure changes in functional statusserving as a surrogate for physical activity and exercise capacityin COPD patients receiving treatment with Spiolto ® Respimat®,at least for 6 weeks, embedded in a real life practice setting.

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

1300 patients with chronic obstructive pulmonary disease (COPD) in whom combination treatment with
long-acting bronchodilators is indicated in accordance with the guidelines are to be observed by approx.
100 pulmonologists in the setting of private 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)

Estimated number of subjects

1300

Study design details

Setting

It is planned that data of approximately 1300 patients from approximately 102 sites (around 100
pulmonologists in private practice and 2 hospital sites) throughout Greece will be collected. Each
investigator (site) will include 10-15 consecutive patients for whom he/she decided for a treatment with
Spiolto ® Respimat®
A log of all patients included into the study (i.e. having given informed consent)

will be maintained in
the ISF at the investigational site irrespective of whether they have been treated or not.

Outcomes

The primary outcome is to measure the proportion of patients achieving the “therapeutic success” defined as a ≥ 0.4 point of increase in the Clinical COPD Questionnaire (CCQ) score (specifically functional status subdomain of CCQ) between baseline and week 6. - Absolute change in the CCQ- Absolute change in CCQ-4.- Physician´s Global Evaluation (PGE) score at baseline and end of study.- Patient satisfaction with (tiotropium and olodaterol) Respimat® at end of study using a seven-point ordinal scale (ranging from very dissatisfied to very satisfied) of the PASAPQ.- Patient preference HH vs RMT (PASAPQ)

Data analysis plan

All patients who have received at least one dose of Spiolto® Respimat® will be included in the analyses, this is the treated set. All analyses will be performed on the treated set (as treated analysis). If patients have missing values for an outcome, those patients will be excluded for that outcome’s analysis. For example, if a patient is missing the CCQ score at Visit 1 and/or Visit 2, that patient will be excluded from the analyses for the primary endpoint of therapeutic success and the secondary endpoint of change in CCQ from Visit 1 to Visit 2.The statistical characteristics presented in the end-of-text tables will be N / mean / SD / min / median / max for continuous variables. Tabulations of relative and absolute frequencies will be presented for categorical variables. Incidence rates and 95% CI will be given when appropriate.

Documents

Study results

1237-0073_Synopsis.pdf (216.1 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