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

**First published:** 26/10/2017

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Study Planned

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/21423

**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**

Planned

# Research institutions and networks

## Institutions

### Boehringer Ingelheim

**First published:** 01/02/2024

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Institution

# Contact details

**Study institution contact**

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**Study contact**

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**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

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**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

**Name of medicine, other**

Spiolto Respimat

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**Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

**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)

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**Estimated number of subjects**

1300

## Study design details

**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.

# 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