Quality of life and preference of COPD patients after Switching from Tiotropium monotherapy (Spiriva® Handihaler®) to dual therapy with Tiotropium bromide plus Olodaterol (Spiolto® Respimat®) under real life conditions in Greece (ELLACTO II study)

First published: 17/03/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS38426

Study ID

44280

DARWIN EU® study

No

Study countries

☐ Greece

Study description

Non-interventional 3-months prospective, two visits, single-cohort, multicenter, nationwide study in patients with stable COPD under maintenance therapy with tiotropium monotherapy (Spiriva® Handihaler®) who, according to their treating physician, have recently required a switch (within one week) to dual therapy with tiotropium bromide plus olodaterol (Spiolto® Respimat®) in the Greek private and public sector pulmonary offices and clinics. The primary objective is to evaluate changes within 3 months in quality of life according to health status evaluated with the COPD Assessment Test (CAT) in COPD patients who have recently switched (within one week) from tiotropium monotherapy (Spiriva® Handihaler®) to dual therapy with tiotropium bromide plus olodaterol (Spiolto® Respimat®).

Study status

Ongoing

Contact details

Study institution contact

Maria Katsamani maria.katsamani.ext@boehringer-ingelheim.com

Study contact

maria.katsamani.ext@boehringer-ingelheim.com

Primary lead investigator

Georgios Patentalakis

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 05/03/2019

Study start date
Planned: 15/03/2021

Actual: 18/02/2021

Date of final study report
Planned: 15/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BOEHRINGER INGELHEIM ELLAS SA

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:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Evaluation of quality of life in COPD patients who have recently switched (within one week) from tiotropium monotherapy (Spiriva® Handihaler®) to dual therapy with tiotropium bromide plus olodaterol (Spiolto® Respimat®)

Main study objective:

The primary objective of this non-interventional study (NIS) is to evaluate changes within 3 months in quality of life according to health status evaluated with the COPD Assessment Test (CAT) in COPD patients who have recently switched (within one week) from tiotropium monotherapy (Spiriva® Handihaler®) to dual therapy with tiotropium bromide plus olodaterol (Spiolto® Respimat®).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1500

Study design details

Outcomes

Mean change in patient’s quality of life (QoL) according to the total CAT score within three-months after the switch from Spiriva® Handihaler® to Spiolto® Respimat® according to the daily clinical practice. 1.Change in the proportion of patients with CAT ≥10 (representing impaired health status) within three months after the switch 2.Mean change from baseline in the total EQ VAS within three- months after the switch 3.Proportion of patients that change (improve/worsen) each of the 5 dimensions of the EQ-5D-5L within three-months after the switch

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Data analysis plan

For the primary outcome, mean and 95% confidence interval will be presented. Primary and secondary outcome variables will be summarized and compared between the baseline visit and the 3-months study visit after the switch to tiotropium bromide plus olodaterol (Spiolto® Respimat®). Baseline data analysis will be carried out. Comorbidities, demographic information and clinical characteristics will be described for the overall population. All categorical variables will be summarized in frequency and percentage. For the primary

analysis, no treatment of missing data is planned except the imputation using the last-observation carried forward LOCF method if any post-baseline value is available in patients who discontinued before three months and for whom the value will be set as the last available measure. Sensitivity analysis will be considered using multiple imputation if more than 25% of missing values exist for a specific variable.

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