Changes in functional status in patients with COPD during therapy with Spiolto® Respimat® (Ellacto study)

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Study Ongoing

Administrative details

EU PAS number

EUPAS28719

Study ID

28720

DARWIN EU® study

No

Study countries

Greece

Study description

This study aims to investigate functional status of COPD patients treated with Spiolto ® Respimat® by means of the CCQ questionnaire, more specifically by its ‘functional status’ subdomain (CCQ-4).

Study status

Ongoing

Research institutions and networks

Institutions

Metropolitan Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

EPAMEINONDAS KOSMAS

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/11/2017

Study start date
Planned: 01/03/2018

Actual: 19/03/2018

Date of final study report
Planned: 30/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BOEHRINGER INGELHEIM ELLAS SA

Study protocol

ELLACTO Protocol 9.1.2019.pdf (791.61 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 type:

Non-interventional study

Scope of the study:

Other

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

QoL evaluation

Main study objective:

The primary objective of this NIS is to measure changes in health and functional status using the CCQ score, in COPD patients on treatment with Spiolto® Respimat® after approximately 6 weeks.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TIOTROPIUM BROMIDE MONOHYDRATE

OLODATEROL HYDROCHLORIDE

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)

Estimated number of subjects

1.363

Study design details

Outcomes

The secondary objectives are to evaluate the absolute change in the CCQ and CCQ-4 between Visit 1 (baseline visit at the start of the study) and Visit 2 (final visit at the end of the study, approx. 6 weeks after Visit 1), the patient’s general condition (physician’s evaluation) at Visit 1 and at Visit 2, as well as patient satisfaction

Data analysis plan

Primary endpoint: proportion of patients achieving “therapeutic success” (= 0.4 point decrease in the CCQ score between baseline and week 6) R17-0254.0.4 points is the well accepted MCID R17-0256 Secondary endpoints:Absolute change in the CCQ Absolute change in CCQ-4.Patient´s general condition: 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) (abbreviated PASAPQ Part 1).Patient preference HH (HandiHaler) vs RMT (Respimat) Inhaler devices – only for those patients that used Spiriva HH previous to the study (PASAPQ Part 2).Treatment continuation of Spiolto® Respimat® after the study.

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