Patient characteristics and treatment pathways in patients with COPD initiated on ICS/LABA/LAMA and LABA/LAMA treatment

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106492

EU PAS number

EUPAS106491

Study ID

106492

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A historical cohort study to describe patient characteristics and 5-year treatment pathways prior to initiation on ICS/LABA/LAMA (triple therapy) and LABA/LAMA (dual bronchodilator) therapy in real-world clinical settings in the United Kingdom

Study status

Planned

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility** **ENCePP partner**

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 14/08/2024

Network | ENCePP partner

Contact details

Study institution contact

E Nudo

Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/10/2022

Study start date

Planned: 18/10/2022

Date of final study report

Planned: 29/12/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Chiesi Pharma, OPRI

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:

Disease epidemiology

Drug utilisation

Main study objective:

To describe patient characteristics and 5-year treatment pathways prior to initiation on triple therapy and dual bronchodilator therapy

Study Design

Non-interventional study design

Cohort

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

128003

Study design details

Outcomes

Descriptive only – primary objective describes the patient characteristics of those initiating on: ICS/LABA/LAMA (free and fixed triple), LABA/LAMA (free and fixed dual bronchodilator), TRIMBOW (fixed triple) initiated as first ever triple

therapy treatment and LABA/LAMA (fixed dual bronchodilator only), Descriptive only– secondary objective describes the treatment pathways in the 5 years prior to treatment initiation (defined as the maximal therapy prescribed within each 1-year period) for a 5 year period prior to initiation on ICS/LABA/LAMA, LABA/LAMA and TRIMBOW

Data analysis plan

In order to describe patient characteristics, statistical differences between the patients split into cohorts will be assessed for those initiating on the following treatments between 2013 – 2023: A) ICS/LABA/LAMA (free and fixed triple) B) LABA/LAMA (free and fixed dual bronchodilator) C) Extra fine ICS/LABA/LAMA (fixed triple) initiated as first ever triple therapy treatment. D) LABA/LAMA (fixed dual bronchodilator only) Treatment pathways will be mapped in the 5 years prior to the date of treatment initiation. The pathways will be mapped as the sum of therapies prescribed during each 1 year period, with the 5 years prior to treatment initiation. Common treatment pathways will be identified based on the number of patients ≥1% of the total study population following a particular pathway. Pathways followed by <1% of patients will be grouped together and presented as other non-frequent pathways

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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