Evidence in real world for Trixeo® Aerosphere™ Initiation in COPD (ENARXI)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106901

EU PAS number

EUPAS106900

Study ID

106901

DARWIN EU® study

No

Study countries

France

Study description

The main aim of the study is to describe the characteristics of COPD patients when Trixeo® Aerosphere™ is initiated, based on data from the THIN® and Colibri databases. Secondary objectives are: - To describe from THIN® database data the rate of appropriate initiation of Trixeo® Aerosphere™ according to: - The Transparency Commission (CT) (18); - SPLF 2021 (5) and GOLD 2021 (4) recommendations. - To describe from THIN® database data the distribution of blood eosinophil count in patients initiating Trixeo® Aerosphere™. - To describe the characteristics of COPD patients initiating treatment with Trixeo® Aerosphere™ using data from the Colibri-BPCO cohort to compare the results obtained with THIN® data and supplement them with patients seen mainly by hospital and private lung specialists and potentially more severe.

Study status

Ongoing

Research institution and networks

Institutions

Cegedim Health Data (CHD)

France

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Adrien Coriat

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/07/2021

Study start date

Actual: 01/09/2021

Date of final study report

Planned: 31/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Regulatory

Was the study required by a regulatory body?

Yes

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:

Drug utilisation

Main study objective:

The main aim of the study is to describe the characteristics of COPD patients when Trixeo® Aerosphere™ is initiated, based on data from the THIN® database.

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 (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

600

Study design details

Data analysis plan

No hypotheses will be tested and no assumptions will be made in this analysis. Continuous variables will be described using mean and standard deviation for parametric variables, median and interquartile range for non-parametric variables. Ordinal, binomial and categorical variables will be described using numbers and proportions.

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

Colibri

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