Real-world use of Breztri/Trixeo for the management of COPD in a UK primary care population

First published: 24/03/2023

Last updated: 15/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS104156

Study ID

104157

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Background/Rationale: The current, stepwise management approach of patients with stable chronic obstructive pulmonary disease (COPD) involves the use of long-acting beta-agonists (LABA), long-acting muscarinic antagonists (LAMA), and/or inhaled corticosteroids (ICS) depending on patients' disease severity and symptomatology. In particular, dual therapies, namely LAMA+LABA or ICS+LABA, are recommended for highly symptomatic patients with moderate to severe COPD. Nonetheless, some patients remain symptomatic and suffer from exacerbations despite using dual therapies. Hence, recent years have seen the emergence of triple therapies (LABA+LAMA+ICS), such as budesonide/glycopyrrolate/formoterol (Breztri/Trixeo). Following demonstration of efficacy by randomized controlled trials, Breztri/Trixeo has been approved by the United States' Food and Drug Administration on 23rd July 2020,7 and by the European Medicines Agency on 9th December 2020. Nevertheless, as a new medication, real-life evidence underlying the safety, acceptability, and efficacy of Breztri/Trixeo is lacking. Given that findings from randomized controlled trials may only be applicable to a subset of patients in real life, this study seeks to investigate the patient acceptability and describe clinical outcomes of Breztri/Trixeo amongst patients with COPD in the early period after launch using a large general practice database in the United Kingdom. Objective: To describe the acceptability and clinical outcomes of Breztri/Trixeo amongst patients with COPD.

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/10/2022

Study start date
Planned: 01/11/2022

Data analysis start date
Planned: 07/11/2022

Date of final study report
Planned: 31/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astra Zeneca

Study protocol

Protocol v6.2.pdf (2.04 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

OPRI-2202, D5980R00073

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe the acceptability and clinical outcomes of Breztri/Trixeo amongst patients with COPD.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AL11) formoterol, glycopyrronium bromide and budesonide

formoterol, glycopyrronium bromide and budesonide

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)

Estimated number of subjects

750

Study design details

Outcomes

The primary outcome will be medication success assessed at 90 days (early medication success) after Breztri/Trixeo initiation, which will be as no major cardiac and respiratory events (MACRE) and no pneumonia, 1. patient demographic and clinical characteristics at initiation, 2. changes in CAT score, 3. factors associated with the primary outcome CAT change at 90 days, 4. medication success assessed at 180 days, 5. short-acting beta-agonist use, 6. acceptability of medication change, 7. adherence, 8. overall number of inhalers used, 9. change in COPD control and in exercise capacity at 90 days

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Data analysis plan

Primary and exploratory outcomes will be summarised as means, medians or percentages as appropriate with 95% confidence intervals. For the primary outcome, medication success will be claimed if the lower 95% confidence limit

for the percentage achieving success is ≥ 70%, assessed at 90 days after Breztri/Trixeo initiation. Exploratory outcomes will be summarised separately for 90 days and 180 days. Additionally, an exploratory analysis will be carried out to try to identify factors associated with the primary outcome (early medication success) and with change in CAT score at 90 days.

Documents

Study results

Trixeo Report v3.2.pdf (2.25 MB)

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 source(s)

Optimum Patient Care Research Database

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