MulTinational database cohoRt study to assess adverse cardIovascular and cereBrovascular outcomes in patiEnts (TRIBE) with chronic obstructive pulmonary disease

First published: 19/05/2022

Last updated: 24/06/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS47420

Study ID

47421

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland

- [ ] Germany
- [ ] Netherlands
- [ ] Norway
- [ ] Sweden
- [ ] United Kingdom

Study description

TRIBE is a non-interventional, multicountry post-authorization safety study (PASS) based on retrospectively collected data. The study will be conducted to investigate the incidence of adverse cardiovascular and cerebrovascular events among patients with chronic obstructive pulmonary disease (COPD) treated Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via DPI (drug of interest), and with patients treated with Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via pMDI (comparator). All data will be collected from pre-existing large longitudinal healthcare databases from 7 countries with secondary use of data. The study will start from the date of the first launch of Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via DPI within the study countries and will continue for up to end of 2026. Interim and progress reports will be produced yearly until the end of 2027 when final study report will be delivered.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fabian Hoti

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2021

Actual: 01/06/2021

Study start date

Planned: 31/12/2022

Actual: 02/12/2022

Data analysis start date
Planned: 31/12/2023

Actual: 31/12/2023

Date of interim report, if expected
Planned: 31/05/2024

Actual: 10/05/2024

Date of final study report
Planned: 31/12/2027

Sources of funding

- Other

More details on funding

Chiesi Farmaceutici S.p.A

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Investigate the incidence of adverse cardiovascular and cerebrovascular events among patients treated Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via DPI, compared with patients treated with Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via pMDI.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BECLOMETASONE DIPROPIONATE

FORMOTEROL FUMARATE DIHYDRATE

GLYCOPYRRONIUM BROMIDE

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

25000

Study design details

Outcomes

To assess the incidence of MACEs and compare it between Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium DPI cohort and pMDI cohort. MACEs will be defined as any of the following events: Myocardial infarction, Stroke (ischemic and haemorrhagic stroke), Hospitalization due to acute coronary syndrome, Hospitalization due to heart failure, To assess the incidence of each of the following events individually: myocardial infarction, cerebrovascular disorders, hospitalization due to acute coronary syndrome, hospitalization due to heart failure, arrhythmia, and all-cause death.

Data analysis plan

In the analysis, crude and adjusted incidence rates (95% CIs) of the composite primary outcome (MACE) and of each secondary outcome will be estimated seperately for new users of Fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium DPI (drug of interest) and Fixed triple therapy pMDI (comparator) for each data source. Exposure and

follow-up time will be defined using an as-treated definition. Crude and adjusted incident rates will be computed using Poisson regression, for adjustment, weighted Poisson regression with inverse-probability-of-treatment weights based on propensity scores will be employed. Propensity scores will be estimated using a logistic regression model with demographic and lifestyle, health care utilization, COPD severity and other medical history variables as covariates. Pooled incidence rate ratio (IRR) estimates will be obtained by combining data-source level IRR estimates using a fixed-effects meta-analysis approach.

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)

Administrative healthcare records (e.g., claims)

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