Cohort study to estimate incidence of pneumonia in users of Trelegy 100 or multiple inhaler triple therapy among patients with chronic obstructive pulmonary disease using health insurance claims data provided by Medical Data Vision Co., Ltd. in Japan (212606)

First published: 04/01/2022

Last updated: 17/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS44882

Study ID

48198

DARWIN EU® study

No

Study countries

Japan

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/03/2022

Study start date
Planned: 29/04/2022

Actual: 20/04/2022

Date of final study report
Planned: 29/08/2024

Actual: 30/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

gsk-212606-protocol-orig-redact.pdf (1.19 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Compare the occurrence of hospitalization due to community-acquired pneumonia (CAP) among patients with COPD who were incident users of Trelegy 100 or MITT.
Hazard ratio (HR) will be calculated to investigate if the risk of CAP in Trelegy 100 group is not higher than a certain level (HR>3) compared to MITT group.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TRELEGY ELLIPTA

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

FLUTICASONE FUROATE

UMECLIDINIUM

VILANTEROL

Anatomical Therapeutic Chemical (ATC) code

(R03AL08) vilanterol, umeclidinium bromide and fluticasone furoate

vilanterol, umeclidinium bromide and fluticasone furoate

Medical condition to be studied

Chronic obstructive pulmonary disease

Pneumonia

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

4.000

Study design details

Outcomes

Community-acquired pneumonia (CAP)

Data analysis plan

Risk estimation

Documents

Study report

Study Report Anonymised 22 Jan 2025.pdf (303.86 KB)

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)

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