Trelegy Ellipta general drug use investigation (asthma)

First published: 05/05/2021

Last updated: 03/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS40313

Study ID

44600

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Post-marketing surveillance to collect and assess information regarding the safety and effectiveness of Trelegy Ellipta in asthma patients under the actual use conditions.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/07/2021

Study start date
Planned: 30/07/2021

Actual: 08/07/2021

Date of final study report
Planned: 31/12/2024

Actual: 08/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-214953-protocol-redact.pdf (191.27 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The objective of this investigation is to collect and assess information regarding the safety and effectiveness of Trelegy Ellipta in asthma patients under the actual use conditions.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational Post-marketing surveillance

Study drug and medical condition

Medicinal product name

TRELEGY ELLIPTA

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

FLUTICASONE FUROATE

UMECLIDINIUM

VILANTEROL TRIFENATATE

Anatomical Therapeutic Chemical (ATC) code

(R03AL08) vilanterol, umeclidinium bromide and fluticasone furoate

vilanterol, umeclidinium bromide and fluticasone furoate

Medical condition to be studied

Asthma

Population studied

Age groups

- Adolescents (12 to < 18 years)
- 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)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

Estimated number of subjects

300

Study design details

Outcomes

Information regarding the safety and effectiveness of Trelegy Ellipta in asthma patients under the actual use conditions.

Data analysis plan

Patient characteristics, Occurrence of ADR (proportion and person-year), Proportion of responders in the overall assessment of effectiveness, Consideration of covariates by logistic regression model

Documents

Study report

Clinical_Study_Report_Anonymised.pdf (6.21 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 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