Post-authorisation Safety (PAS) Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium (Study 201038)

First published: 17/07/2015

Last updated: 06/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10316

Study ID

107565

DARWIN EU® study

No

Study countries

Belgium
Czechia
Germany
Hungary
Italy
Netherlands
Poland
Spain
United Kingdom
United States

Study description

The study will address the research question of whether the incidence rates of cardiovascular (CV) and cerebrovascular events differ for new users of umeclidinium bromide/vilanterol trifenatate (UMEC/VI) combination or umeclidinium bromide (UMEC) compared with tiotropium in patients diagnosed with Chronic Obstructive Pulmonary Disease (COPD).

Study status

Finalised

Research institutions and networks

Institutions

Quintiles

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Real World Solutions, IQVIA

Netherlands

United Kingdom (Northern Ireland)

First published: 28/04/2011

Last updated: 22/03/2024

Institution | Other | ENCePP partner

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: 01/05/2015

Actual: 01/05/2015

Study start date
Planned: 02/02/2016

Actual: 02/02/2016

Date of final study report
Planned: 10/11/2023

Actual: 21/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201038-protocol-redact.pdf (1.29 MB)

gsk-201038-protocol-amend4-redact.pdf (1.52 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

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 primary objectives are: 1. To demonstrate non-inferiority of UMEC/VI combination and UMEC to tiotropium for risk of myocardial infarction (MI), stroke, heart failure or sudden cardiac death based on analysis to time to first event. 2. To quantify incidence rate and frequency of MI, stroke, heart failure or sudden cardiac death for new users of UMEC/VI combination, UMEC, and tiotropium.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TIOTROPIUM BROMIDE MONOHYDRATE

UMECLIDINIUM BROMIDE

VILANTEROL TRIFENATATE

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

7.214

Study design details

Outcomes

Safety outcomes reported will include MI, stroke and new onset, or acute worsening/decompensation heart failure, sudden cardiac death, serious pneumonia/serious LRTI events, all-cause mortality, CV mortality and non-CV mortality, haemorrhagic stroke and ischaemic stroke, hospitalisation for heart failure, SAEs, all serious CV AESIs and all drug related AEs. Treatment effectiveness outcomes recorded will include persistence with initiated medications, moderate/severe COPD exacerbations (requiring treatment with one or more of the following: antibiotics, systemic steroids, hospitalisation) and health care utilisation: all cause and COPD-related.

Data analysis plan

The analysis will compare new users of UMEC/VI with new users of tiotropium, and new users of UMEC with new users of tiotropium. These new treatments may be added on to existing therapies. Analyses will be based on the time to the first event of stroke, MI and heart failure individually and non-inferiority will be considered to be demonstrated if the upper bound of the 95% confidence interval around the hazard ratio is 2.0 or less. If the lower bound is greater than 1.0, non-inferiority will not be assumed.

Documents

Study report

Clinical Study Report Anonymized 29 Jan 2024.pdf (2.88 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