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: 12/06/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/107565

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
Ongoing

Research institution 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
ENCePP partner
Other

Contact details

Study institution contact
GSK Clinical Disclosure Advisor
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:
30/09/2015
Actual:
02/02/2016

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

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

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
7214

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

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