Post-authorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting

First published: 23/10/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41147

EU PAS number

EUPAS7761

Study ID

41147

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study primarily aims to collect data reflecting the real-world experience with UMEC/VI and UMEC in the post-approval setting (period of up to 24 months from the start of UMEC/VI and UMEC availability in the United Kingdom). The study will use a retrospective longitudinal non-interventional observational study design to identify patients based on a new prescription (index prescription date) for UMEC/VI, UMEC, or other long acting bronchodilators (LABD). These patients will be followed-up from their index prescription date until censoring at death, leaving practice, or end of follow-up at 30 June 2017.

Study status

Finalised

Research institutions and networks

Institutions

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution **Laboratory/Research/Testing facility** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Dedman

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/06/2014

Actual: 04/06/2014

Study start date

Planned: 01/03/2015

Actual: 11/09/2014

Date of final study report

Planned: 31/12/2019

Actual: 10/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

117397-protocol-redact (UPDATED).pdf(803.72 KB)

gsk-117397-protocol-redact-v02.pdf(602.21 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

This study primarily aims to collect data reflecting the ‘real-world’ experience with umeclidinium/vilanterol (UMEC/VI) and umeclidinium (UMEC) in the post-approval setting. UMEC/VI and UMEC as well as other medications containing only long-acting bronchodilators (LABD) are indicated for the treatment of Chronic Obstructive Pulmonary Disease (COPD).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective longitudinal non-interventional observational study

Study drug and medical condition

Name of medicine

ANORO

INCRUSE

LAVENTAIR

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The main study population consisted of new users of UMEC/VI, UMEC or Other LABD with ‘acceptable’ data quality in the CPRD-GOLD and THIN databases. Patients were labelled as ‘acceptable’ if they had continuous follow up and did not meet criteria for poor data recording.

Inclusion criteria:

1. A record for a new prescription of UMEC/VI, UMEC, or Other LABD between July 1, 2014 and June 30, 2016 (inclusive).
2. At least 12 months of registration at a practice with ‘up to standard data’ recording prior to index prescription date to allow characterization of patient’s status, demographics and clinical characteristics. Data were considered ‘up to standard’ when the GP practice had continuous high-quality data fit for use in research.

Exclusion criteria:

1. A prescription for the same specific inclusion medication (or combination) of LABD ever recorded in the past. Prior or concomitant use of respiratory medications containing a different specific active substance (or combination) than the new substance initiated was allowed.

Age groups

Children (2 to < 12 years)

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)

Estimated number of subjects

2000

Study design details

Outcomes

Off-label use, defined as prescribing in patients without a recorded diagnosis of COPD. 1. The frequency of Myocardial infarction, Heart failure, Stroke, Pneumonia, Death, COPD exacerbations 2. Treatment patterns (discontinuation, switch or augmentation) and medication adherence (Medication Possession Ratio (MPR) and Proportion of Days Covered (PDC)

Data analysis plan

Primary Outcome: Among new users of UMEC/VI, UMEC, or other LABD, calculate the proportion with off label use according to presence or absence of a COPD diagnosis record.Secondary Outcomes: Among new users of UMEC/VI or UMEC, calculate the incidence (new events/person-time) of myocardial infarction, heart failure, stroke, death, pneumonia/lower respiratory tract infections, and exacerbations of COPD.Among new users UMEC/VI or UMEC, describe treatment patterns (discontinuation, switching and augmentation) and adherence to treatment using medication possession ratio proportion of days

covered during the 0-12 months of follow-up.

Documents

Study results

gsk-117397-clinical-study-report-final-redact.pdf(5.75 MB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

SIGNED - Declaration of Interests.pdf(267.13 KB)

Composition of steering group and observers

Study Scientific Committee.pdf(54.96 KB)

Signed code of conduct

2014-0029_ Declaration on Compliance_SDPP-7761.pdf(159.77 KB)

Signed code of conduct checklist

2014-0029_CoC Checklist_SDPP-7761.pdf(509.16 KB)

Signed checklist for study protocols

2014-0029_Protocol Checklist_SDPP-7761 r.pdf(528.08 KB)

ENCEPPChecklistForProtocols_20160924_signed.pdf(2.47 MB)

Data sources

Data source(s)

Clinical Practice Research Datalink

THIN® (The Health Improvement Network®)

Data source(s), other

Office for National Statistics (ONS) Mortality statistics, Clinical audit databases managed by the National Institute for Cardiovascular Outcomes research (NICOR): including the Myocardial Infarction National Audit Program (MINAP) and Cardiac Rhythm Management database

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