Drug utilisation study of new users of fluticasone furoate / vilanterol (FF/VI) in the primary care setting: UK Clinical Practice Research Datalink (CPRD) study (205052)

First published: 07/02/2017

Last updated: 18/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17720

Study ID

48241

DARWIN EU® study

No

Study countries

United Kingdom

Study description

In the 24-months following the availability of fluticasone furoate / vilanterol (FF/VI) in the United Kingdom, this study will identify new users of FF/VI or other inhaled-corticosteroid/long-acting beta-2-agonist (ICS/LABA) fixed dose combination (FDC) medications from primary care Electronic Medical Records database. Objectives: 1. Separately among new users of FF/VI and other ICS/LABA FDC, describe patient characteristics (incl. demographics, disease burden, selected comorbidities and respiratory medication use) and diagnosis group (asthma, COPD-including an asthma history stratification, other). 2. Among new users of FF/VI, describe off-label prescribing including: • FF/VI 200/25 (pre-dispensed doses, all doses in mcg) formulation in patients with evidence of a COPD diagnosis (only FF/VI 100/25 is licensed for use in patients with COPD) • FF/VI (any dose) in children <12 years of age (neither FF/VI 200/25 nor FF/VI 100/25 is licensed for use in children <12 years of age) 3. Among new users of FF/VI, describe the treatment patterns and adherence to therapy by diagnosis group.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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

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

Planned: 29/07/2016

Actual: 29/07/2016

Study start date
Planned: 01/03/2017

Actual: 04/04/2017

Date of final study report
Planned: 31/07/2017

Actual: 15/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-205052-protocol-redact.pdf (350.66 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Off-label use

Data collection methods:

Secondary use of data

Main study objective:

Off-label use and treatment patterns of FF/VI as well as patient characteristics will be evaluated in study with the use of UK primary care Electronic Medical Records (EMR) database

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, longitudinal, non-interventional, observational study

Study drug and medical condition

Medicinal product name

RELVAR

REVINTY ELLIPTA

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

FLUTICASONE FUROATE

VILANTEROL TRIFENATATE

Anatomical Therapeutic Chemical (ATC) code

(R03AK10) vilanterol and fluticasone furoate

vilanterol and fluticasone furoate

Medical condition to be studied

Chronic obstructive pulmonary disease

Asthma

Population studied

Short description of the study population

The main study population consisted of new users of FF/VI or other ICS/LABA FDC medications with ‘acceptable’ data quality in CPRD-GOLD. Patients are labelled as ‘acceptable’ if they have continuous follow up and do not meet criteria for poor data recording.

Inclusion criteria:

- Record of a new prescription of FF/VI or other ICS/LABA FDC during the inclusion period (January 1, 2014 through December 31, 2015).
- ≥ 12 months of registration at a practice with ‘up to standard data’ recording prior to index prescription date to allow for characterization of patient’s status, demographics and clinical characteristics. Data are considered ‘up to standard’

when the GP practice has continuous high quality data fit for use in research.
Exclusion criteria:
- Patients were excluded if they had ever had a prescription for the same specific inclusion medication prior to the index prescription. Prior use of another ICS/LABA FDC product was permitted. All available data prior to the index date was used to ascertain new use of FF/VI and other ICS/LABA FDC. Concomitant use of respiratory medications was allowed.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- 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

4.220

Study design details

Outcomes

Patient characteristics (including demographics and clinical characteristics), off-label prescribing, treatment patterns and adherence to therapy.

Data analysis plan

Objective 1Among the new users of FF/VI or other ICS/LABA FDC patient demographics, comorbidities and disease history characteristics at date of index prescription will be summarised by diagnosis group. Objective 2Among the new users of FF/VI calculate the proportion with off label use according to pre-specified definitions.Objective 3Among the new users of FF/VI describe treatment patterns (discontinuation, switching and augmentation) and adherence to treatment using medication possession ratio proportion of days covered during follow-up.

Documents

Study results

gsk-205052-clinical-study-report-redact.pdf (3.94 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 source(s)

Clinical Practice Research Datalink

Data sources (types)

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