An open label, multi-centre, post marketing surveillance (PMS) to monitor the safety and effectiveness of ANORO administered in Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice (204511)

First published: 26/10/2015

Last updated: 26/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11397

Study ID

50502

DARWIN EU® study

No

Study countries

Korea, Democratic People's Republic of

Study description

As a condition of the product approval, the PMS is assigned from national regulatory authority. It’s to monitor the safety and effectiveness of ANORO administered in 3000 Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 40 centres are involved in the study

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: 23/04/2015

Actual: 23/04/2015

Study start date

Planned: 30/11/2015

Actual: 30/10/2015

Date of final study report

Planned: 09/10/2020

Actual: 18/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-204511-protocol-redact.pdf (332.97 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 type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To collect safety and effectiveness data of Anoro in Korean COPD patients

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open-label, single arm, multi-centre post marketing surveillance (PMS)

Study drug and medical condition

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

VILANTEROL TRIFENATATE

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients with chronic obstructive pulmonary disease (COPD) aged 19 years or older received ANORO under usual clinical practice in Korea.

Inclusion criteria:

 Adult subjects (19 years and older) who have chronic obstructive pulmonary disease (COPD)

- Pulmonary Function Test: post bronchodilator, FEV1/FVC < 0.7

 Subjects who will administer ANORO according to locally approved prescribing information

Exclusion criteria:

 Asthma patient

 Subject with acute exacerbation of COPD

 Subject who experienced hypersensitivity to the active substances or to any of the excipients

 Subject with severe hypersensitivity to milk proteins

 Subject with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

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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

Other

Renal impaired

Special population of interest, other

Patients with chronic obstructive pulmonary disease

Estimated number of subjects

3.000

Study design details

Outcomes

Incidence of adverse events, incidence of unexpected adverse events and incidence of serious adverse events after administrating ANORO, Effectiveness after administrating ANORO, as determined by post BD FEV1 on Treatment Week 24

Data analysis plan

The number and percentage of subjects with an adverse event, including SAE and/or unexpected AE, after administration of ANORO will be presented. Cases with serious adverse events and/or unexpected adverse drug reactions will be described in detail. The percentage of subjects reporting adverse events will be analyzed using Chi-square test or Fisher’s exact test stratified by potential confounding factors such as gender, age, smoking history, BMI, baseline lung function test(FEV1)before administration, COPD treatment, disease history, exacerbation history and others for subgroup analysis. Effectiveness evaluation will be stratified by potential confounding factors.

Documents

Study results

gsk-204511-clinical-study-report-redact.pdf (9.29 MB)

Study publications

Cho EY, Cho JE, Lee EB, Yoo SS, Chang JH. An Open-Label, Multicentre, Observati...

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)

Electronic healthcare records (EHR)

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