Meta-Analysis Plan for MID207941: A Study to Evaluate Risk Factors for Pneumonia and Chronic Obstructive Pulmonary Disease (COPD) Exacerbations in a COPD Population of Patients Treated with GW685698 + GW642444 (Fluticasone Furoate + Vilanterol); GW642444 (Vilanterol); CCI18781 (Fluticasone Propionate); GR33343 (Salmeterol); CCI18781+ GR33343 (Fluticasone Propionate + Salmeterol) and Placebo

First published: 23/10/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21362

Study ID

48226

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This is a meta-analysis. The purpose of this meta-analysis is to evaluate the most important risk factors, alone and in combination for pneumonia and chronic obstructive pulmonary disease (COPD) exacerbations in patients with COPD. The analysis will identify the subgroups of COPD patients which are most at risk for these events and quantify the probability of patients having those events.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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

Actual: 03/07/2017

Study start date

Actual: 03/07/2017

Date of final study report

Planned: 18/09/2018

Actual: 06/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-207941-reporting-and-analysis-plan-redact.pdf (120.46 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

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

Data collection methods:

Secondary use of data

Main study objective:

Evaluates the most important risk factors, alone and in combination for pneumonia and chronic obstructive pulmonary disease (COPD) exacerbations in patients with COPD. Expanding on known risks provided in RMP

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medicinal product name

RELVAR

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients with COPD.

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

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

10946

Study design details

Outcomes

Time to first pneumoniaTime to first moderate/severe exacerbation

Data analysis plan

Model estimated probability of eventHazard ratios for each covariate in the model

Documents

Study results

Additional information for 207941.pdf (92.6 KB)

gsk-207941-clinical-study-report-redact.pdf (8.7 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

Data from GSK Sponsored Completed Clinical Trials: HZC102870, HZC102970, SCO100250, SCO40043, SCO30003

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