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

PURI
https://redirect.ema.europa.eu/resource/48226

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 institution and networks

Institutions

GlaxoSmithKline (GSK)
First published: 01/02/2024
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Institution

Contact details

Study institution contact
GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor
Study contact

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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 data collection

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

Name of medicine
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

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