Multinational, multi-database drug utilization study of indacaterol/glycopyrronium bromide in Europe

First published: 30/10/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7795

Study ID

39607

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Italy
- ☐ Netherlands

Spain

United Kingdom

Study description

Multinational, multi-database drug utilization study of indacaterol/glycopyrronium bromide in Europe

Study status

Finalised

Research institutions and networks

Institutions

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Networks

EU-ADR Alliance

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Novartis Clinical Disclosure Officer
Trialandresults.registries@novartis.com

Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/12/2013

Study start date

Actual: 01/11/2013

Data analysis start date

Planned: 03/11/2014

Actual: 11/03/2014

Date of interim report, if expected

Planned: 02/02/2015

Date of final study report

Planned: 31/10/2017

Actual: 05/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

QVA149A2401-v03--protocol_2_Redacted.pdf(1.19 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CQVA149A2401

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:

The proportion of patients using QVA149 who do not meet criteria specified in the QVA149 label (‘off-label use’) i.e. use in patients younger than 18 years or in patients without a diagnosis of COPD, with asthma/asthma and COPD without concomitant use of inhaled corticosteroids (ICS)* -Proportion of patients using QVA149 who have missing information as per RMP or high risk treatment conditions

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

INDACATEROL

GLYCOPYRRONIUM BROMIDE

Anatomical Therapeutic Chemical (ATC) code

(R03AL04) indacaterol and glycopyrronium bromide

indacaterol and glycopyrronium bromide

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The study population will comprise of all patients who newly initiated therapy with QVA149, as recorded in the databases. Initiation of therapy will be defined as a first prescription or dispensing of QVA149 preceded by at least 1 year of QVA149-free valid database history. The date of the first prescription of QVA149 will be defined as index date.

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

3000

Study design details

Data analysis plan

The study will not test any a priori hypothesis.Descriptive statistics will be used and categorical data will be presented in counts (n) and proportions (%) with 95% confidence intervals (95% CIs). 95% CIs will be calculated either based on the normal distribution or based on the binomial distribution. For continuous data, the number of observations (n), mean, standard deviation and median (with inter-quartile range) will be presented.Switching characteristics will be described by counts, proportions and 95% CI both from switching from QVA149 to another respiratory drug (LABA, LAMA, LABA+ICS, loose combination LABA+LAMA, loose combination LABA+ICS, loose combination LAMA+ICS or triple therapy) and vice versa.

Documents

Study results

QVA149A2401-Redacted-Final-Study-Report.pdf(2.23 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)

THIN® (The Health Improvement Network®)

Health Search/IQVIA Health Longitudinal Patient Database

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

Aarhus University Prescription Database (DK)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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