Multinational database cohort study to assess RMP specified safety outcomes in association with indacaterol/glycopyrronium bromide in Europe

First published: 28/10/2014

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37308

EU PAS number

EUPAS7674

Study ID

37308

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

Multinational database cohort study to assess RMP-specified safety outcomes in association with indacaterol/glycopyrronium bromide in Europe

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Health Search, Italian College of General Practicioners

- [ ] Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

SIDIAP Jordi Gol Spain

Networks

EU-ADR Alliance

First published: 01/02/2024

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Network

Contact details

Study institution contact

Clinical Disclosure Office Novartis

Study contact

Trialandresults.registry@novartis.com

Primary lead investigator

Clinical Disclosure Officer Novartis

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

Date of interim report, if expected

Planned: 20/02/2015

Date of final study report

Planned: 28/12/2018

Actual: 03/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

QVA149A2402-v02--protocol_redacted.pdf(1.67 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Other study registration identification numbers and links

CQVA149A2402

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:

To assess the incidence rates and relative risks of selected endpoints in association with QVA149 exposure in a broader, real-world COPD population.

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

Population of patients ≥40 years of age with at least one year of valid database history and a recorded diagnosis of COPD. Valid database history means that there is at least one year of database history for a patient. This means that the patient was registered with the GP since at least one year but also that the GP is providing data to the database for at least one year as well. For all patients an eligibility date will first be defined, which is the latest of the following dates: reaching 40 years of age, having one year of data in the database and having fulfilled the criteria for a diagnosis of COPD. Diagnoses of COPD may be searched in the entire available prior history of a patient.

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

6000

Study design details

Outcomes

Primary endpoints of interest are 1) Major cardiovascular events (myocardial infarction (MI) stroke, hospitalizations due to acute coronary syndrome orheart failure), 2) Ischemic heart disease including MI and angina pectoris, 3) cerebrovascular events (ischemic stroke, hemorrhagic stroke and (TIA)), 4) Cardiac arrhythmias (atrial fibrillation/flutter and ventricular arrhythmia, The secondary endpoints of interest are 1) (Narrow-angle) Glaucoma, 2) Bladderobstruction/urinary retention/incident BPH, 3) Diabetes Mellitus, 4) Bronchospasmand 5) all-cause mortality

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Data analysis plan

Cox regression will be used to estimate both crude and adjusted relative risks (expressed as hazard ratios HRs with 95% CIs), allowing for time-varying exposures.All analyses will be performed for each database separately. Effect estimates will be pooled across the databases, using a random effects approach. In addition, a pooled mega-analysis will be done by combining the data sources on a patient-level and adjusting for the database.As secondary analysis, subsequent episodes, with or without treatment, will be taken into account. The anchor drug will be used as reference category, HRs of the events will be estimated for all other treatment categories compared to this reference. In addition, a sensitivity analysis will be conducted only considering the first treatment episode during follow-up in patients naïve to both QVA149 and all

comparator drugs.Specific patient groups will be studied via stratified analysis on age, gender,underlying CV co-morbidity and COPD severi

Documents

Study results

qva149a2402--legacy-clinical-study-report-redacted_Part1.pdf(6.99 MB)

Study report

qva149a2402--legacy-clinical-study-report-redacted_Part2.pdf(5.97 MB)

Data management

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