Angioedema among patients with hypertension treated with aliskiren or other anti-hypertensive medications in the US – a cohort Study and a nested case-control analysis using health claims data

First published: 15/10/2013

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4963

Study ID

17554

DARWIN EU® study

No

Study countries

United States

Study description

Retrospective database cohort study including a nested case-control analysis with secondary use of data from the IMS PharMetrics PlusTM claims database from the United States in adult hypertensive patients (18+ years of age) with a prescription for an anti-hypertensive medication of interest between July 1, 2007 and September 30, 2012. The primary objective is to assess the annual prevalence and incidence rates of angioedema in treated hypertensive patients among a commercially insured population, stratified by the anti-hypertensive medication filled. The secondary objective is to explore the relative risk of experiencing angioedema among patients prescribed aliskiren compared with other anti-hypertensive medications.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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: 20/12/2012

Study start date
Actual: 22/08/2013

Data analysis start date
Actual: 22/09/2013

Date of final study report
Planned: 31/01/2014

Actual: 20/02/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CSPP100A2415-Redacted-Protocol_15Aug2013.pdf (3.22 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

CSPP100A2415

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 annual prevalence and incidence rates of angioedema in treated hypertensive patients (with focus on aliskiren)

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medicinal product name

RASILAMLO

RASILEZ HCT

Medical condition to be studied

Hypertension

Population studied

Short description of the study population

All adult hypertensive subjects with a prescription for an anti-hypertensive medication of interest between July l, 2007 and September 30, 2012 derieved from IMS PharMetrics PlusTM US claims database.

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

Hypertensive patients

Estimated number of subjects

45.000

Study design details

Outcomes

A diagnosis of angioedema, based on the ICD-9 code (i.e. ICD-9code 995.1) from medical claims, The secondary objective is to explore the relative risk of experiencing angioedema among patients prescribed aliskiren compared with other anti-hypertensive medications

Data analysis plan

Prevalence: A one-year period prevalence of angioedema will be calculated for the calendar years 2008-11. The denominator will consist of the aggregate person-time (expressed in years) of all patients who were continuously enrolled for at least one month in the calendar year of interest.Incidence: Similarly, the incidence of angioedema will be calculated for each of calendar years 2008-11. The denominator for incidence determination will consist of the aggregate person-time (expressed in years) of all patients who were continuously enrolled for at least one month in the calendar year of interest as well as the full preceding calendar year. The numerator of the incidence estimate will be determined by identifying all patients with a diagnosis of angioedema during the calendar year of interest. In order to be considered an incident patient, there must additionally be no evidence of angioedema diagnoses during the preceding calendar year(s). per 1,000 patient-years of follow-up

Documents

Study results

SPP100A2415-Redacted-Final-Study-Report.pdf (1.45 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), other

IMS PharMetrics Plus Health Plan Claims Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown