A multi-database cohort study to assess the incidence rates of colorectal hyperplasia among hypertensive patients

First published: 27/12/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8295

Study ID

17564

DARWIN EU® study

No

Study countries

Italy

Netherlands

Spain

United Kingdom

Study description

This study will estimate the frequency of colorectal polyps, cysts and neoplasms among hypertensive patients. Age- and sex-specific incidence rates will be estimated as well as the time from hypertension diagnosis to colorectal polyps, colorectal cysts and colorectal neoplasms.This multi-database dynamic cohort study, in four European primary care databases (CPRD, IPCI, CPRD, SIDIAP), includes all adult patients (aged 18-79 years) with an incident diagnosis of arterial hypertension.Incidence rates will be calculated by dividing the total number of incident cases over the total number of person-years at risk within the study population for each database separately.. Standardization of incidence rates will be performed using either a European reference population or by internal validation using one of the four databases as reference population to which the other three databases will be compared to.Kaplan Meier analyses will be performed to estimate the survival time from arterial hypertension diagnosis date until one of the primary safety endpoints (colorectal polyps, cysts or neoplasms) but also for each of the endpoints separately.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Clinical Disclosure Officer Novartis

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Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Clinical Disclosure Officer Novartis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2015

Actual: 09/01/2015

Study start date

Planned: 01/01/2015

Actual: 15/05/2015

Date of final study report

Planned: 01/01/2016

Actual: 14/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CSPP100A2417-Redacted-Protocol.pdf (637.02 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CSPP100A2417

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

This study will estimate the frequency of colorectal polyps, cysts and neoplasms among hypertensive patients. Age- and sex-specific incidence rates will be estimated as well as the time from hypertension diagnosis to colorectal polyps, colorectal cysts and colorectal neoplasms.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ALISKIREN HEMIFUMARATE

Anatomical Therapeutic Chemical (ATC) code

(C09XA) Renin-inhibitors

Renin-inhibitors

Medical condition to be studied

Essential hypertension

Accelerated hypertension

Hypertension

Blood pressure increased

Blood pressure orthostatic increased

Blood pressure measurement

HELLP syndrome

Blood pressure ambulatory increased

Blood pressure diastolic increased

Blood pressure systolic increased

Population studied

Short description of the study population

Adult patients (aged 18-80 years) in the individual databases with an incident diagnosis of arterial hypertension between January 01, 2000 and December 31, 2012.

Patients with continuous enrollment in the database for at least 1 year prior to the start of follow-up, aged 18 years or older at the start of follow-up and diagnosis of arterial hypertension were included.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

Special population of interest

Other

Special population of interest, other

Arterial hypertension patients

Estimated number of subjects

10.000

Study design details

Outcomes

Incidence of colorectal polyps, cysts and neoplasms among hypertensive patients.

Data analysis plan

Incidence rates will be calculated by dividing the total number of incident cases over the total number of person-years at risk within the study population for each database separately.. Standardization of incidence rates will be performed using either a European reference population or by internal validation using one of the four databases as reference population to which the other three databases will be compared to.Kaplan Meier analyses will be performed to estimate the survival time from arterial hypertension diagnosis date until one of the primary safety endpoints (colorectal polyps, cysts or neoplasms) but also for each of the endpoints separately.

Documents

Study results

SPP100A2417-Redacted-Final-Study-Report.pdf (1.1 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)

Clinical Practice Research Datalink

Health Search/IQVIA Health Longitudinal Patient Database

The Information System for Research in Primary Care (SIDIAP)

German Pharmacoepidemiological Research 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