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

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# Administrative details

#### PURI

https://redirect.ema.europa.eu/resource/17564

#### **EU PAS number**

EUPAS8295

#### **Study ID**

17564

#### DARWIN EU® study

No

#### **Study countries**

∣ltaly

Netherlands

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 First published: 01/02/2024 Last updated: 01/02/2024

Institution

# Contact details

#### Study institution contact

**Clinical Disclosure Officer Novartis** 

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

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#### Study topic:

**Study type:** 

Disease /health condition Human medicinal product

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

10000

# 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

# Data management

# 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