Incidence of colorectal hyperplasia and gastrointestinal cancer in treated adult hypertensive patients in the United States – a cohort study based on secondary use of health data

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**Study status** 



### Administrative details

EU PAS number		
EUPAS7828		
Study ID		
-		
17572		
DARWIN EU® study		
No		
Study countries		
United States		

### Research institutions and networks

### **Institutions**

### **Novartis Pharmaceuticals**

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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

Planned: 25/06/2013

Actual: 25/06/2013

#### Study start date

Planned: 01/11/2014

Actual: 01/07/2014

#### **Date of final study report**

Planned: 30/06/2015

Actual: 27/05/2015

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Novartis Pharma Services AG

# Study protocol

SPP100A2418-v0--protocol-revised-24Mar14PRACapproved 20140703\_Redacted.pdf (627.43 KB)

CSPP100A2418-Redacted-Protocol.pdf (754.21 KB)

# 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

CSPP100A2418

# 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 determine age- and sex-stratified incidence rates of colorectal hyperplasia and gastrointestinal (GI) cancer in adult hypertensive patients exposed to aliskiren and other antihypertensive drugs other than aliskiren, as well as in a sample of patients without a diagnosis of hypertension and without antihypertensive drug use.

# 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

Accelerated hypertension

Blood pressure ambulatory increased

Blood pressure diastolic increased

Blood pressure inadequately controlled

Blood pressure orthostatic increased

Blood pressure management

Blood pressure systolic increased

Diastolic hypertension

# Population studied

#### Short description of the study population

Using the index window from 1 January 2007 through 31 December 2012, patients (for the treatment groups) were selected into the study cohort if they (1) have at least 1 prescription for an antihypertensive medication (the first such prescription will be defined as a patient's index date), (2) evidence of at least 1 hypertension diagnosis (ICD-9-CM codes 401.xx-405.xx) in 180-day preindex, (3) are 18+ years of age at the time of the index date, and (4) have continuous health plan enrollment for a minimum of 180 days prior to the index date and a minimum of 180 days following the index date. Individuals for the general population control group will be selected into the study cohort if they have (1) no prescriptions for an antihypertensive medication between 1 July 2006 and 30 June 2013 (2) no evidence of a hypertension diagnosis (ICD-9-CM codes 401.xx-405.xx) any time between 1 July 2006 and 30 June 2013), (3) are 18+ years of age at the time of the index date, and (4) have continuous health plan enrollment for a minimum of 180 days prior to the index date and a minimum of 180 days following the 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

Hypertensive patients

#### **Estimated number of subjects**

10000

# Study design details

#### **Outcomes**

Incidence of colorectal hyperplasia and GI cancer among treated hypertensive patients and a sample of patients without hypertension, Relative risk of colorectal hyperplasia and GI cancer among hypertensive patients (treated by aliskiren versus antihypertensive drugs other than aliskiren) and a sample of patients without hypertension

#### Data analysis plan

All data will be reported for the aggregate antihypertensive treatment population (treated by aliskiren and other antihypertensive drugs) as well as stratified by the incident vs. prevalent antihypertensive treatment cohorts, and the general population control cohort. For the primary analyses, incidence rates with 95% confidence intervals will be calculated per 100,000 person-years for colorectal hyperplasia and GI cancer. These rates will be reported by age group and gender, as well as by index antihypertensive drug cohort and antihypertensive drug cohort from index date to prior to the end of follow-up. For the secondary analyses, relative risks will be estimated using Cox proportional hazards models for colorectal hyperplasia and GI cancer among hypertensive patients exposed to aliskiren vs. hypertensive patients exposed to

antihypertensive drugs other than aliskiren and vs. a general population sample without a diagnosis of hypertension and without antihypertensive drug use.

### **Documents**

#### **Study results**

SPP100A2418-Redacted-Final-Study-Report.pdf (2.17 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 LifeLink: PharMetrics Plus - US

### **Data sources (types)**

Administrative healthcare records (e.g., claims)

# Use of a Common Data Model (CDM)

### **CDM** mapping

# Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

Unknown