Assessing the Incidence of Ischemic Colitis in Treated Adult Hypertensive Patients in the United States – a Descriptive, Retrospective Cohort Study with Secondary Use of Data from a US Health Claims Database (NA)

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### Administrative details

**EU PAS number** 

EUPAS4568

Study ID

17559

**DARWIN EU® study** 

No

**Study countries** 

#### Study description

Descriptive, retrospective cohort study with secondary use of data derived from the PharMetricsTM Health Plan Claims Database from 1 July 2005 through 30 June 2012 (or the most recent data available at the time of data extraction). The objective of this study is to assess the incidence of probable ischemic colitis (defined as evidence of a recorded diagnosis of ischemic colitis within 3 months after a colonoscopy, rectosigmoidoscopy or a colectomy) in treated hypertensive patients (focusing on patients using aliskiren) and by demographic characteristics, antihypertensive therapy use over the follow-up period, and adherence to antihypertensive therapy. Additionally, we will also look for incidence of probable ischemic colitis within a sample of the general population (patients without a diagnosis of hypertension or antihypertensive drug use).

#### **Study status**

Finalised

# Research institutions and networks

### Institutions

### **Novartis Pharmaceuticals**

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Institution

## **Novartis Pharmaceuticals**

### 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: 02/07/2013

#### Data analysis start date

Actual: 05/08/2013

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

Planned: 30/09/2013

Actual: 13/09/2013

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Novartis Pharma AG

# Study protocol

CSPP100A2416-Redacted-Protocol\_26Jun2013.pdf (3.16 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

CSPP100A2416

# 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 of probable ischemic colitis in treated hypertensive patients (with focus on aliskiren)

# Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine

**RASILEZ** 

#### Medical condition to be studied

Hypertension

# Population studied

#### Short description of the study population

Adult hypertensive subjects with a prescription for an antihypertensive medication between January 1, 2006 and March 31,2012.

Subjects were included who had evidence of a hypertension diagnosis (ICD-9-CM codes 401."M-405.yeO; the date of the first hypertension diagnosis will be considered the diagnosis date; At least I prescription for an antihypertensive medication within 180 days of the diagnosis date OR with at least one days supply overlapping the diagnosis date; 18 years of age or older at the time of the index date; Continuous health plan enrollment for a minimum of 180 days prior to the index date (pre-index period) and a mimmum of 90 days of continuous enrollment following the index date (post-index period).

#### 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**

20000

# Study design details

#### **Outcomes**

Probable ischemic colitis (defined by ICD-9-CM and CPT-4 codes, using inpatient and outpatient claims as evidence of a recorded diagnosis of ischemic colitis (ICD-9-CM code 557.xx) within 3 months after a colonoscopy (CPT-4 codes 45378-45387), a rectosigmoidoscopy (CPT-4 codes 45330-45331, 45340-45342, 45300, 45303, 45305) or a colectomy (CPT-4 codes 44140-44160).

#### Data analysis plan

Incidence of ischemic colitis will be calculated per 100,000 person-years (PYs) and presented as incidence rates (IRs) with 95% confidence intervals (CIs). These rates will be reported by age group and gender as well as by index antihypertensive drug cohort (stratified by age group and gender), antihypertensive drug cohort prior to the end of follow-up (stratified by age and gender), and by adherence (using medication possession ratio or MPR, defined later in this document) to the index antihypertensive therapy and to any antihypertensive therapy. Additional IRs that take into account patients' varying exposure to antihypertensive medications will be calculated per person-time contributed to each drug classification.

### **Documents**

#### Study results

SPP100A2416-Redacted-Final-Study-Report.pdf (1.46 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 sources (types)**

Administrative healthcare records (e.g., claims)

Other

#### Data sources (types), other

PharMetricsTM Health Plan Claims Database, USA

# Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

#### **Check stability**

### **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No