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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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/17559

EU PAS number
EUPAS4568

Study ID
17559

DARWIN EU® study
No

Study countries
United States

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 institution and networks

Institutions

Novartis Pharmaceuticals
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Institution

Novartis Pharmaceuticals

Contact details

Study institution contact
Novartis Clinical Disclosure Officer
Study contact

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Primary lead investigator
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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 data collection

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 prescnption 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

Data sources

Data sources (types)
Administrative data (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
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No