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

First published: 30/10/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7828

Study ID

17572

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

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Study contact

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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

Eclampsia

Endocrine 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 pre-index, (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

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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

10.000

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

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown