A Cohort Study to Assess Various Safety Outcomes of Interest in Users of Aliskiren Using Claims Data

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17549

EU PAS number

EUPAS3577

Study ID

17549

DARWIN EU® study

No

Study countries

☐ United States

Study description

Retrospective database cohort study using US health claims database information to assess whether under real-world conditions aliskiren – either as monotherapy or in combination – may be associated with a risk increase of certain outcomes of interest as identified in ALTITIUDE compared to other antihypertensive drugs. The study objectives are as follows: To quantify associations between aliskiren and the occurrence of select outcomes. This will involve quantification of incidence rates and relative risks of (i) cerebrovascular accidents, (ii) transient ischemic attack, (iii) myocardial infarction, (iv) heart failure leading to hospitalization, (v) acute renal failure, and (vi) end stage renal disease (ESRD) in users of aliskiren compared to users of other antihypertensive drugs.Secondary objectives are: To quantify associations between aliskiren and the occurrence of hyperkalemia and hypotension. This study will separately assess the incidence rates and relative risks of (i) hyperkalemia, (ii) hypotension, and (iii) death in users of aliskiren compared to users of other antihypertensive drugs.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Mapi

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/09/2012

Study start date

Actual: 15/02/2013

Data analysis start date

Planned: 30/06/2013

Actual: 01/07/2013

Date of final study report
Planned: 31/03/2014

Actual: 17/03/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CSPP100A2414-Redacted-Protocol_11Mar2013.pdf(3.74 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

CSPP100A2414

Methodological aspects

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 whether under real-world conditions aliskiren – either as monotherapy or in combination with other antihypertensives (especially with ACEIs or ARBs) – may be associated with an increased risk of certain outcomes of interest as identified in ALTITIUDE compared to other antihypertensive drugs

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Resilez

Study drug International non-proprietary name (INN) or common name

ALISKIREN

ALISKIREN HEMIFUMARATE

Medical condition to be studied

Hypertension

Population studied

Short description of the study population

Members of the two U.S. data sources: (1) US MarketScan® Commercial Claims and Encounters database and Medicare Supplement provided by Novartis and (2) UnitedHealth Research Database provided by Brigham and Women’s Hospital as patients who have a first-time recorded dispensing between 1 March 2007 and 31 December 2011 (or latest available from each data source) for aliskiren (aliskiren cohort) or another antihypertensive drug.
Patients at least 18 years old at the time of the first prescription for aliskiren or other antihypertensive drug and who have at least one prescription for aliskiren or another antihypertensive drug, at least 6 months of continuous enrollment prior to (and inclusive of the date of) the first prescription for aliskiren or another antihypertensive drug (to form the baseline period), valid data for age and sex, at least one inpatient or outpatient ICD-9 diagnosis code of hypertension (401.xx -
405.xx) during the baseline period were included.

Age groups

Adults (18 to < 46 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Renal impaired

Estimated number of subjects

67000

Study design details

Outcomes

To quantify incidence rates and relative risks of (i) cerebrovascular accidents, (ii) transient ischemic attack (TIA), (iii) myocardial infarction (MI), (iv) heart failure leading to hospitalization, (v) acute renal failure (ARF), (vi) end stage renal disease (ESRD) in users of aliskiren compared to users of other antihypertensive drugs, To quantify associations between aliskiren and the occurrence of hyperkalemia, hypotension, and death. This study will separately assess the incidence rates and relative risks of (i) hyperkalemia, (ii) hypotension, and (iii) death in users of aliskiren compared to users of other antihypertensive drugs.

Data analysis plan

This study will seek to estimate the relative risk (as a hazard ratio HR) of each outcome comparing patients initiating aliskiren to patients initiating other antihypertensive medications. All analyses will be conducted in propensity score matched cohorts to achieve a high degree of multivariate confounding control. In addition, although many analyses on the outcomes will be performed, no formal adjust for multiple comparisons will be done. Rather than hypothesis testing, this study aims to estimate the association of aliskiren with study outcomes relative to comparison treatments across numerous exposures

and exposure subgroups. Estimates and 95% confidence intervals (CIs) for each comparison will be presented without adjustment for multiplicity, and these 95% CIs can be interpreted individually as including the true association value approximately 95% of the time, even where multiple comparisons have been made.

Documents

Study results

SPP100A2414-Redacted-Final-Study-Report.pdf(3.99 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

US MarketScan® Commercial Claims and Encounters database and Medicare Supplement, UnitedHealth Research 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