Aliskiren Prescription Event Monitoring Study (Aliskiren PEM)

First published: 14/04/2014

Last updated: 16/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/6339

EU PAS number

EUPAS6338

Study ID

6339

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This postmarketing observational Prescription-Event Monitoring (PEM) study was designed to examine the safety and use of the renin inhibitor, aliskiren (Rasilez®), prescribed in general practice in England, licensed for the treatment of essential hypertension. Patients were identified from dispensed National Health Service (NHS) prescription data for aliskiren between February 2008 and November 2010. A questionnaire was sent to the prescribing GP at least 6 months after the prescription was issued, requesting standard prescribing and patient information, as well as details of any events suffered by the patient during and after stopping treatment with aliskiren.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

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Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/08/2008

Study start date

Actual: 01/02/2008

Date of final study report

Planned: 25/01/2013

Actual: 25/01/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To examine the safety of aliskiren used in general medical practice in England which is licensed as a treatment for essential hypertension.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

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

ALISKIREN

Population studied

Short description of the study population

Patients prescribed with aliskiren (Rasilez®) in general practice between February 2008 and November 2010 in England

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Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

6385

Study design details

Data analysis plan

PEM methodology provides a numerator (the number of reports of an event) and a denominator (the number of patient-months at risk), both collected within a known time frame. This allows for the calculation of risk (percent of total valid cohort exposed) and incidence densities (ID, person-time incidence rates) for each event. Such analyses will be performed using ‘Higher-level’ event terms from the DSRU drug dictionary.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring

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