

# Aliskiren Prescription Event Monitoring Study (Aliskiren PEM)

**First published:** 14/04/2014

**Last updated:** 16/02/2024

Study

Finalised

## Administrative details

### 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.

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## 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**

[saad.shakir@dsru.org](mailto:saad.shakir@dsru.org)

## Primary lead investigator

Saad Shakir

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 08/08/2008

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### Study start date

Actual: 01/02/2008

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### 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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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## **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)

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## **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](#)

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#### Data sources (types), other

Prescription event monitoring

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No