An Observational Study to Evaluate the Potential Association Between Cinacalcet and Gastrointestinal Bleeding (20170171)

First published: 28/02/2018

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26219

EU PAS number

EUPAS21914

Study ID

26219

DARWIN EU® study

No

Study countries

☐ United States

Study description

An observational study to assess the potential association between cinacalcet use and risk of gastrointestinal bleeding in patients receiving maintenance hemodialysis.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Chronic Disease Research Group (CDRG)

Minneapolis, MN, USA

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/12/2016

Actual: 22/12/2016

Study start date

Planned: 02/03/2018

Actual: 02/03/2018

Data analysis start date

Planned: 19/03/2018

Actual: 19/03/2018

Date of final study report

Planned: 01/09/2018

Actual: 07/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

20170171_Public Redacted Protocol Ver 1.0 2018-02-12 English.pdf(1.82 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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:

This nested case control study is designed to address the FDA requirement by assessing the potential association between cinacalcet use and the risk of fatal and non-fatal GI bleeding among hemodialysis patients using the linked DaVita-USRDS database.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

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

CINACALCET

Medical condition to be studied

Hyperparathyroidism secondary

Population studied

Short description of the study population

Hemodialysis patients who, between 2007 and 2010, satisfy the following criteria:

1. Age ≥ 18 years
2. At least 91 days on hemodialysis
3. Covered by Medicare Parts A, B, and D for at least 365 days
4. Received hemodialysis for at least 91 days in a DaVita dialysis facility
5. Parathyroid hormone (PTH) >300 pg/mL during the baseline period
6. No cinacalcet use for 365 days (baseline period)
7. No GI bleeding event for 365 days (baseline 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

Renal impaired

Estimated number of subjects

12000

Study design details

Outcomes

The primary outcomes is the composite event of fatal and non-fatal GI bleeding.

Data analysis plan

Descriptive statistics will be used to compare cases and controls, with respect to demographic, comorbidity and medication use characteristics. The odds of exposure among case and controls will be calculated. Conditional logistic regression will be used to estimate the OR and associated 95% confidence interval (CI) for the association between cinacalcet use and risk of fatal and non-fatal GI bleeding adjusting for other potential confounders. If the upper limit of the 95% confidence interval of the estimated OR is less than 1.3, the conclusion will be that cinacalcet use is not associated with an elevated relative risk of fatal or non-fatal GI bleeding.

Documents

Study results

ORSR abstract 20170171.pdf(86.58 KB)

Data management

Data sources

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