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

First published:
28/02/2018
Last updated 01/04/2024
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
First published:
01/02/2024
Last updated 21/02/2024
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