

# 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>

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### EU PAS number

EUPAS21914

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### Study ID

26219

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### DARWIN EU® study

No

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### Study countries

United States

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## Study description

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

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Amgen](#)

United States

**First published:** 01/02/2024

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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](mailto: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

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**Study start date**

Planned: 02/03/2018

Actual: 02/03/2018

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**Data analysis start date**

Planned: 19/03/2018

Actual: 19/03/2018

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**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

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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:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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

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**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  $\geq$  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)
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## **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)

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## **Special population of interest**

Renal impaired

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## **Estimated number of subjects**

12000

# Study design details

## **Outcomes**

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

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## 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)

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## 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

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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**

Unknown