

# Cinacalcet Use and the Risk of Gastrointestinal (GI) Bleeding Among Hemodialysis Patients with Secondary Hyperparathyroidism (SHPT) in DOPPS

**First published:** 09/04/2018

**Last updated:** 26/06/2019

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/30274>

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### **EU PAS number**

EUPAS23268

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### **Study ID**

30274

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### **DARWIN EU® study**

No

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## Study countries

United States

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## Study description

The rate of GI bleeding in the 2013 US Medicare hemodialysis population was 23 per 1,000 patient-years (PYs), while the mortality rate from GI bleeding was 0.91 per 1,000 PYs. In placebo-controlled trials, the rate of GI bleeding in hemodialysis patients was similar in the etelcalcetide group (2.0%) and the placebo group (2.1%). We will conduct an observational study to address the possibility of a potential association between calcimimetics and fatal and non-fatal GI bleeding in a population of hemodialysis patients.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

**Last updated:** 21/02/2024

Institution

## 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: 26/10/2017

Actual: 14/03/2018

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### **Study start date**

Planned: 01/05/2018

Actual: 01/05/2018

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### **Data analysis start date**

Planned: 01/09/2018

Actual: 01/09/2018

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### **Date of final study report**

Planned: 30/06/2019

Actual: 24/06/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen, Inc.

## Study protocol

[EUPAS23268-23566.pdf](#)(433.84 KB)

## 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

Disease /health condition

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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:**

1: Estimate the association between exposure to cinacalcet and the risk of hospitalization from GI bleeding, by region and overall.2. Estimate the association between exposure to cinacalcet and the risk of death from GI bleeding, by region and overall.3: Estimate the rate of hospitalization from GI bleeding and the rate of death from GI bleeding, by region and overall.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

MIMPARA

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

CINACALCET HYDROCHLORIDE

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## **Anatomical Therapeutic Chemical (ATC) code**

(H05BX01) cinacalcet

cinacalcet

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## **Medical condition to be studied**

Gastrointestinal haemorrhage

## Population studied

### **Short description of the study population**

Patients aged  $\geq 18$  years who had received in-center hemodialysis at a Dialysis Outcomes and Practice Patterns Study (DOPPS) facility.

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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**

10000

## Study design details

## Outcomes

GI bleeding in a hospital setting and death from GI bleeding

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### Data analysis plan

Descriptive statistics using mean and standard deviation (SD) or median and 25th/75th percentile estimates for continuous variables (as appropriate) and number and percentages (n, %) for categorical variables will be used to examine patient characteristics in a cohort of subjects with SHPT who are on dialysis. We will estimate the hazard ratio (HR) and 95% CI for the association of cinacalcet exposure and risk of an inpatient hospitalization for GI bleeding (or death from GI bleeding), implemented using conditional logistic regression analysis for standard matched case-control studies. We will estimate the crude incidence rates of hospitalization for GI bleeding or crude death rates from GI bleeding and associated 95% CIs using the Poisson model.

## Documents

### Study results

[20170665\\_Observational Research Study Report - Cinacalcet Use and the Risk of Gastrointestinal Bleeding abstract.pdf](#)(154.41 KB)

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## Data management

### Data sources

#### Data sources (types)

[Disease registry](#)

### 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