# Characterizing the management of hypocalcemia among European hemodialysis patients receiving cinacalcet (20150330)

**First published:** 24/01/2017

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS17390

**Study ID**

23682

**DARWIN EU® study**

No

**Study countries**

Czechia

France

Hungary

- Ireland
- Italy
- Poland
- Portugal
- Romania
- Russian Federation
- Serbia
- Slovakia
- Slovenia
- Spain
- Türkiye
- United Kingdom

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**Study description**

Hypocalcemia is a common adverse event in hemodialysis (HD) patients with secondary hyperparathyroidism (sHPT) receiving cinacalcet as first-line treatment. Patients using cinacalcet are six times more likely to experience hypocalcemia (total calcium <8.4 mg/dl) compared to those who do not use it. Any side effects such as hypocalcemia could adversely affect a patient’s level of medication compliance and/or adherence or changes in treatment strategies (e.g. dose reduction or discontinuation of cinacalcet). Calcium-containing phosphate binders, vitamin D sterols and/or adjustment of dialysis fluid calcium concentrations can be used to raise serum calcium according to clinical judgment. Dose reduction or cinacalcet discontinuation may negatively affect SHPT control. To date, treatment strategies to manage cinacalcet-induced hypocalcemia have not been well-characterized in a European HD population. In addition, it is unclear whether patients who recover from hypocalcemia will achieve adequate SHPT control. Data are needed to inform appropriate treatment guidance on the management of hypocalcemia among SHPT patients using cinacalcet.Therefore, we propose to characterize clinician treatment and

management practices of hypocalcemia in a retrospective observational cohort study (Analysing Data, Recognizing Excellence and Optimising Outcomes Research initiative, AROii cohort) of incident European HD patients with sHPT who were prescribed cinacalcet.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

**Last updated:** 27/03/2026

**Institution**

# Contact details

**Study institution contact**

Global Development Leader Amgen Inc.
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**Study contact**

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**Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 01/04/2016

**Study start date**
Planned: 30/01/2017

Actual: 30/01/2017

**Data analysis start date**
Planned: 01/02/2017

Actual: 24/04/2017

**Date of final study report**
Planned: 31/03/2018

Actual: 23/04/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

Protocol 20150330_2016-12-19.pdf (1.74 MB)

# Regulatory

**Was the study required by a regulatory body?**

No

**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:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Describe prescribing patterns of cinacalcet at time of cinacalcet initiation, at time of hypocalcemia event and after hypocalcemiaDescribe prescribing patterns of any treatment intervention (e.g. vitamin D, phosphate binders, and cardiovascular medications) at time of cinacalcet initiation, at time of hypocalcemia and after hypocalcemiaIdentify factors associated with changes to any treatment

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective cohort study

## Study drug and medical condition

**Medicinal product name**

MIMPARA

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

CINACALCET

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**Anatomical Therapeutic Chemical (ATC) code**

(H05BX01) cinacalcet

cinacalcet

**Medical condition to be studied**

Hyperparathyroidism secondary

# Population studied

**Short description of the study population**

Adult subjects presenting at one of 304 participating facilities in 14 European countries (Czech Republic, France, Hungary, Ireland, Italy, Poland, Portugal, Romania, Russia, Serbia, Slovak Republic, Slovenia, Spain, and United Kingdom) and Turkey enrolled between 01 January 2007 and 31 December 2009.

**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**

1200

# Study design details

**Outcomes**

No change, dose reduction, discontinuation or dose increase of cinacalcet or any treatment intervention (e.g. vitamin D, phosphate binders and CVD medications) after hypocalcemia event, To describe characteristics of cinacalcet patients who do and do not develop hypocalcemiaAmong patients who discontinued cinacalcet following hypocalcemia, to describe factors associated with cinacalcet re-initiation

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**Data analysis plan**

Point estimates and 95% confidence intervals will be derived to determine the rate of cinacalcet discontinuation and changes to disease related prescribing patterns following a hypocalcemic event Time to first hypocalcemia event, time to any treatment intervention following hypocalcemia event, and time to cinacalcet re-initiation will be estimated using Kaplan Meier methods according to baseline calcium levels. Cox regression models will be used to identify baseline covariates associated with time to first occurrence of hypocalcemia during the first 12 months of the study, time to any treatment intervention during the 12 months following hypocalcemia event and time to cinacalcet re-iniation during the 12 months following cinacalcet discontinuation. Hazard ratios and 95% confidence intervals will be calculated.

## Documents

**Study results**

ORSR abstract 20150330.pdf (152.47 KB)

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# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Routine database for hemodialysis patients

# 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