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

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# 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

## **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
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Institution

# Contact details

## **Study institution contact**

Global Development Leader Amgen Inc. medinfo@amgen.com

Study contact

medinfo@amgen.com

**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

# 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

## 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 hypocalcemialdentify factors associated with changes to any treatment

# Study Design

## Non-interventional study design

Other

## Non-interventional study design, other

Retrospective cohort study

# Study drug and medical condition

## **Medicinal product name**

**MIMPARA** 

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

**Anatomical Therapeutic Chemical (ATC) code** 

#### 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)</li>
- 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

#### 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 reiniation 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)

# 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