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

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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

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

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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

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

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

(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

1.200

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)

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