

# An Observational Registry Study To Evaluate The Use And Safety Of Cinacalcet Among Paediatric Patients With Secondary Hyperparathyroidism (20180204)

**First published:** 16/08/2018

**Last updated:** 20/11/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS24954

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### Study ID

38179

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### DARWIN EU® study

No

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### Study countries

- Austria
- Belgium
- Czechia

- France
  - Germany
  - Greece
  - Italy
  - Portugal
  - Spain
  - United Kingdom
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### Study description

This is a non-interventional observational registry of paediatric patients receiving maintenance dialysis with sHPT and using cinacalcet. A patient will receive standard of care treatment as determined by the patient's physician.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Amgen

- United States

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

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

Institution

## Bordeaux University Hospital (CHU de Bordeaux)

France

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

**Last updated:** 01/02/2024

**Institution**

Hospital/Clinic/Other health care facility

## University Medical Centre Hamburg-Eppendorf

Germany

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

**Last updated:** 01/02/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

## Motol University Hospital (FNM)

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

**Last updated:** 01/02/2024

**Institution**

## Heidelberg University Hospital

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

**Last updated:** 01/02/2024

## Ghent University Hospital

Belgium

**First published:** 20/11/2025

**Last updated:** 20/11/2025

Institution

Hospital/Clinic/Other health care facility

- Universitaetsklinikum Allgemeines Krankenhaus Wien (Vienna General Hospital)
- Universitair Ziekenhuis Leuven (UZ Leuven) - Campus Gasthuisberg
- Hopital Universitaire des Enfants Reine Fabiola (Queen Fabiola Children's University Hospital)
- Universite Catholique de Louvain, Cliniques Universitaires Saint Luc
- Clinique Centre Hospitalier Chrétien MontLégia
- Hospices Civils de Lyon
- Hopital Femme Mere Enfant

- Hopital des Enfants Centre
- Hospitalier Regional Universitaire de Montpellier
- Hopital Arnaud de Villeneuve
- Hopital Pellegrin
- Centre Hospitalier Universitaire Archet 2
- Kindernierenzentrum Bonn
- Medizinische Hochschule Hannover
- Charite – Universitaetsmedizin Berlin, Campus Virchow
- General Children Hospital Panagioti and Aglaias Kyriakou
- Ippokrateio General Hospital of Thessaloniki
- IRCCS Istituto Giannina Gaslini
- IRCCS Ospedale Pediatrico Bambino Gesù
- Unidade Local de Saude de Sao Jose, EPE
- Hospital Universitari Vall d Hebron
- Royal Hospital for Children Glasgow
- Southampton Children's Hospital
- Royal Manchester Children's Hospital

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

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: 01/04/2019

Actual: 13/06/2018

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### Study start date

Planned: 20/01/2020

Actual: 09/01/2020

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### Data analysis start date

Planned: 09/05/2024

Actual: 09/05/2024

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### Date of interim report, if expected

Planned: 14/11/2022

Actual: 30/03/2023

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

Planned: 31/12/2024

Actual: 07/11/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.02.06 Public Redacted Protocol Ver 1.0 English.pdf](#) (1.03 MB)

[Protocol-Published Amendment cinacalcet hydrochloride 20180204 8.pdf](#) (1.12 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)?**

EU RMP category 3 (required)

# Other study registration identification numbers and links

20180204

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

To describe patient characteristics, how cinacalcet is used, laboratory values over time, the incidence of hypocalcaemia, risk factors associated with time to hypocalcaemia event and management of hypocalcaemia in paediatric patients with secondary hyperparathyroidism (sHPT).

### Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective and prospective chart review 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

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**Medical condition to be studied**

Hypocalcaemia

Hyperparathyroidism secondary

## Population studied

**Short description of the study population**

The registry will enrol eligible paediatric patients on maintenance dialysis who are prescribed cinacalcet treatment.

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**Age groups**

- **Paediatric Population (< 18 years)**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
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### **Estimated number of subjects**

45

## Study design details

### **Outcomes**

In a European cohort of paediatric patients with sHPT on maintenance dialysis and using cinacalcet: To describe the patient characteristics, how cinacalcet is used, the laboratory values (PTH, cCa, phosphate and albumin) over time and the incidence, management and risk factors associated with hypocalcaemia.

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### **Data analysis plan**

There are no formal hypotheses for the study. Descriptive data analyses will be performed. Characteristics of patients who develop and do not develop hypocalcaemia will be described. Treatment characteristics (cinacalcet and other sHPT medications) will be summarised prior to cinacalcet initiation and after a hypocalcaemia event. PTH, cCa, phosphate and albumin laboratory parameters over time will be summarised. To describe time-to-event of first hypocalcaemia event, cinacalcet discontinuation and cinacalcet re-initiation, Kaplan-Meier (KM) curves will be calculated.

## Documents

### **Study report**

[20180204\\_ORSR Abstract\\_21OCT2024\\_Redacted.pdf](#) (1.35 MB)

## 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)

[Disease registry](#)

[Other](#)

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### Data sources (types), other

Routine primary care electronic patient 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