

# A Prospective Cohort Study to Describe Use and Safety of Cinacalcet in Pediatric Patients Receiving Dialysis in the NAPRTCS Registry (20120116)

**First published:** 11/02/2014

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

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/17576>

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### **EU PAS number**

EUPAS5647

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### **Study ID**

17576

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### **DARWIN EU® study**

No

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## Study countries

- Canada
  - Costa Rica
  - Mexico
  - United States
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## Study description

Describe the demographics, laboratory values, and secondary hyperparathyroidism (SHPT) medication use (specifically cinacalcet), and the occurrence of hypocalcemia, seizures, and infections (requiring hospitalization), in cinacalcet treated and untreated patients enrolled in the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) receiving dialysis for chronic kidney disease (CKD).

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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**

# North American Pediatric Renal Trials and Collaborative Studies Boston, MA, USA

## 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

Actual: 22/06/2012

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### Study start date

Actual: 01/08/2012

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### Data analysis start date

Actual: 01/08/2013

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### Date of interim report, if expected

Actual: 01/10/2013

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

Planned: 22/07/2016

Actual: 31/01/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Cinacalcet\\_20120116\\_Protocol\\_11Feb14.pdf\(284.36 KB\)](#)

## Regulatory

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

Yes

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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:**

Disease /health condition  
Human medicinal product

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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  
Disease epidemiology  
Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Describe the demographics, laboratory values, and secondary hyperparathyroidism (SHPT) medication use (specifically cinacalcet), and the occurrence of hypocalcemia, seizures, and infections (requiring hospitalization), in cinacalcet treated and untreated patients enrolled in the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) receiving dialysis for chronic kidney disease.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine, other**

Sensipar

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**Medical condition to be studied**

Central hypothyroidism

## Population studied

**Short description of the study population**

All patients < 21 years of age receiving maintenance dialysis for chronic kidney disease (CKD) at a North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) affiliated center, and who were enrolled in the registry.

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**Age groups**

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**Special population of interest**

Renal impaired

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**Estimated number of subjects**

1000

## Study design details

## **Outcomes**

Demographic characteristics, laboratory values (PTH, calcium, phosphorus), SHPT medication use, occurrence of clinical events (hypocalcemia, seizures, infections requiring hospitalization).

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## **Data analysis plan**

The analyses will describe the study population and outcomes as follows: 1) total number of patients and total number of patient-years observation based on the annual data reporting periods, and for the cumulative 3-year study period, 2) estimation of rates of cinacalcet use based on the annual data reporting periods, and for the cumulative 3-year study period, 3) estimation of rates of AESI based on the annual data reporting periods, and for the cumulative 3-year study period, 4) proportion of patients who received at least 1 dose of cinacalcet within 7 days preceding an episode of hypocalcemia (from amongst all patients who developed hypocalcemia). Descriptive analyses using summary statistics will also be conducted to tabulate baseline demographic and clinical characteristics by cinacalcet-exposed and cinacalcet unexposed. The cinacalcet utilization pattern will also be assessed (eg, dosing, duration of treatment).

## Documents

### **Study results**

[20120116\\_ORSR\\_Abstract.pdf](#)(14.16 KB)

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## Data management

## Data sources

## **Data sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection

## **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**

Unknown