# Characterizing the Management of Hypocalcemia Among Patients on Hemodialysis Receiving Cinacalcet Treated Within a Large US Dialysis Provider (20140132)

**First published:** 21/04/2014

**Last updated:** 07/10/2015

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/11232

**EU PAS number**

EUPAS6210

**Study ID**

11232

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

To compare characteristics (demographic, clinical, and laboratory values) of patients on hemodialysis who develop hypocalcemia while on cinacalcet with the characteristics of patients who do no develop hypocalcemia while on cinacalcet, and to characterize the management of hypocalcemia among patients on hemodialysis receiving cinacalcet using data from the DaVita® Rx database and the DaVita Clinical Data Warehouse patient electronic medical records.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

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Institution

DaVita Clinical Research Minneapolis, Minnesota, USA

## Contact details

**Study institution contact**

Global Development Leader Amgen, Inc

**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: 08/11/2013

**Study start date**

Actual: 14/03/2014

**Data analysis start date**

Planned: 02/05/2014

Actual: 15/10/2014

**Date of final study report**
Planned: 01/05/2015

Actual: 02/10/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

Cinacalcet_20140132_Protocol_21Apr14.pdf(817.25 KB)

## Regulatory

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

No

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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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

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To compare characteristics of patients on hemodialysis who develop hypocalcemia while on cinacalcet with the characteristics of patients who do not develop hypocalcemia while on cinacalcet.To describe patterns of treatment strategies used by physicians.To describe the subsequent recovery of serum calcium.To describe patterns of cinacalcet reinitiation among patients who discontinue.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Hyperparathyroidism secondary

# Population studied

**Short description of the study population**

Patients enrolled in DaVita Rx™ who received hemodialysis at DaVita HealthCare Partners Inc. facilities between 01 January 2011 and 31 December 2013 and filled a prescription of cinacalcet.

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**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)

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**Special population of interest**

Renal impaired

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**Estimated number of subjects**

15000

# Study design details

**Outcomes**

The development of hypocalcemia.The percent of patients receiving specific treatment responses over the first 30-day interval following the index date of

hypocalcemia.The outcome will be the percent of patients who achieve calcium recovery following the index date of hypocalcemia.The percent of patients who re-initiate cinacalcet during the 90 days following cinacalcet discontinuation.

**Data analysis plan**

Descriptive analyses will be conducted for the distributions of demographic, clinical and laboratory values among patients on hemodialysis who develop hypcalcemia. Baseline characteristics of patients who develop hypocalcemia will be compared to patients who do not develop hypocalcemia. Among patients who develop hypocalcemia, we will describe the percentage receiving specific physician responses and the relevant join distributions of physician responses to the hypocalcemic event. Descriptive analyses for the number and percentage of patients who recover to previous calcium levels dependent on the cut-off used to define hypocalcemia, as well as time-to-event analyses for the overall cumulative incidence of calcium recovery and reinitiation of cinacalcet for patients who discontinue use.

## Documents

**Study results**

Reductions_Calcium_ORSR_Final.pdf(583.22 KB)

# Data management

## Data sources

**Data source(s), other**

Da Vita® Rx Database United States, Da Vita Clinical Data Warehouse United States

**Data sources (types)**

Administrative healthcare records (e.g., claims)

## 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

No