

# Calcimimetics Adherence and Preference Study in the Management of Secondary Hyperparathyroidism in Europe

**First published:** 12/03/2019

**Last updated:** 26/04/2022

Study

Finalised

## Administrative details

### EU PAS number

EUPAS27845

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### Study ID

46905

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### DARWIN EU® study

No

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### Study countries

- ☐ Belgium
- ☐ France
- ☐ Germany
- ☐ Italy

- ☐ Spain
  - ☐ Sweden
  - ☐ United Kingdom
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### **Study description**

Data from clinical trials and real-life clinical practice have demonstrated the effectiveness of cinacalcet in reducing PTH. In a controlled clinical trial comparing etelcalcetide with cinacalcet, etelcalcetide was found to be at least as effective as cinacalcet in reducing PTH by more than 30% after a minimum of 20 weeks' treatment, and no difference in adherence was observed. However, the effectiveness of etelcalcetide in clinical practice might be substantially different in real-life clinical practice (e.g. adherence). There are also no data on physician and nurse's calcimimetic preference. Given the lack of real-world data describing medication adherence, preference and consequently achievement of PTH control of etelcalcetide following initial marketing authorization in Europe, the Calcimimetic Adherence and Preference (CAP) study will provide relevant patient-reported outcome (PRO) data from a real-world clinical setting from the patient, nephrologist and dialysis nurse perspective.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Amgen**

- ☐ United States

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

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**Institution**

Multiple centres: 120 centres are involved in the study

## 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: 15/11/2017

Actual: 15/11/2017

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**Study start date**

Planned: 11/10/2019

Actual: 04/10/2019

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**Data analysis start date**

Planned: 25/10/2021

Actual: 09/09/2021

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**Date of final study report**

Planned: 15/04/2022

Actual: 25/04/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20170519\\_01.02.06 Public Redacted Protocol Ver 1.0 2019-02-13 English.pdf](#)

(929.69 KB)

## Regulatory

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

No

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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:**

Human medicinal product

Disease /health condition

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

Evaluation of patient-reported outcomes

#### **Data collection methods:**

Combined primary data collection and secondary use of data

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#### **Main study objective:**

The Calcimimetic Adherence and Preference (CAP) study will provide relevant patient-reported outcome (PRO) data from a real-world clinical setting in terms of patient adherence and preference from the nephrologist and dialysis nurse perspective.

## Study Design

## **Non-interventional study design**

Cross-sectional

Other

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### **Non-interventional study design, other**

A multi-country prospective observational cross-sectional survey of patient, nephrologist and dialysis nurses and (primary data collection) and use of secondary data collected from the European Dialysis Outcomes and Practice Patterns Study

## Study drug and medical condition

### **Medical condition to be studied**

Hyperparathyroidism secondary

## Population studied

### **Short description of the study population**

The study population will consist of adult chronic HD patients who are prescribed oral cinacalcet or IV etelcalcetide at the time they are approached for study participation. Data will be collected via a questionnaire on calcimimetic self-reported adherence (primary data). Nephrologists and dialysis nurses at each participating dialysis facility with experience prescribing and/or administering calcimimetics will complete a questionnaire on calcimimetic preference for management of SHPT. Questionnaires will be piloted prior to the conduct of the study.

In addition, patient and nephrologist questionnaires will be linked with data collected from DOPPS 7 (secondary data) to understand whether there are

clusters of patient (eg, clinical parameters), nephrologist, and facility-level factors that might be associated with patient adherence and nephrologist/dialysis nurse preferences.

## Patients

Adults aged  $\geq 18$ , receiving chronic HD and are prescribed oral cinacalcet or intravenous etelcalcetide at the time they are approached for study participation; and

provide written informed consent according to local requirements. Patients who have been diagnosed with dementia or hospitalized in the last 4 weeks prior to being approached for the study will be excluded.

## Nephrologist and dialysis nurse

The nephrologists and dialysis nurses at participating dialysis facilities with experience prescribing and/or administering calcimimetics will be included.

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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

400

# Study design details

## Outcomes

- To describe the level of self-reported adherence among haemodialysis patients prescribed oral cinacalcet versus IV etelcalcetide for managing SHPT- To describe the level of preference for IV etelcalcetide compared to oral cinacalcet for managing secondary hyperparathyroidism among nephrologists and nurses. To describe treatment persistence of calcimimetics, patient's belief about treatment intrusiveness with calcimimetic adherence, patient's experience of symptoms with calcimimetic adherence, associations between nephrologist/nurse calcimimetic preference and site SHPT management practices, patient-level factors and site level SHPT management practices and associations with calcimimetic adherence.

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## Data analysis plan

Scoring of adherence and preference levels will be carried out according to validated MARS, BMQ-specific, TIS, KDQOL, and HPPS tools. Descriptive statistics (number frequency, mean, median, SD, IQR and range) will be carried out. For models of association, covariates may be entered in hierarchical groups to assess the incremental and overall effects on the outcomes. Quantile categorization and spline regression methods may be used to identify appropriate functional forms of continuous variables. Associations will be reported with either 95% CI or standard error values with p-values.

## Documents

### Study results

[20170519 Observational Research Study Report Abstract\\_Redacted.pdf](#) (169.71 KB)

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## 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

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### Data sources (types), other

HCP survey, secondary data collected from the European Dialysis Outcomes and Practice Patterns Study

## 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