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

Study ID

46905

DARWIN EU® study

No

Study countries

- Belgium
- France
- Germany
- Italy

Spain

Sweden

United Kingdom

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.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

Multiple centres: 120 centres are involved in the study

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

Planned: 15/11/2017

Actual: 15/11/2017

Study start date
Planned: 11/10/2019

Actual: 04/10/2019

Data analysis start date
Planned: 25/10/2021

Actual: 09/09/2021

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Evaluation of patient-reported outcomes

Data collection methods:

Combined primary data collection and secondary use of data

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

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 ≥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.

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

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.

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)

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No