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

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

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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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

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.

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

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

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 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