Effect of Cinacalcet Discontinuation on Biochemical Control for Medicare Beneficiaries with Part D Coverage Treated within a Large US Dialysis Provider (20130335)

First published: 11/02/2014

Last updated: 21/05/2015

Study Finalised

Administrative details

EU PAS number

EUPAS5641

Study ID

9776

DARWIN EU® study

No

Study countries

☐ United States

Study description

To identify risk factors of discontinuation and reinitiation of cinacalcet, and to describe the trajectory of parathyroid hormone, calcium, and phosphorus laboratory values following the discontinuation of cinacalcet following cinacalcet discontinuation using data from the United States Renal Data System including Medicare Part D prescription claims merged with dialysis provider data from DaVita (one of the largest dialysis providers in the US).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

University of North Carolina at Chapel Hill

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Institution

University of North Carolina at Chapel Hill Chapel Hill, NC, USA

Contact details

Study institution contact

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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: 16/09/2013

Study start date

Actual: 01/12/2013

Data analysis start date

Planned: 01/02/2014

Date of final study report
Planned: 01/02/2015

Actual: 20/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Cinacalcet_20130335_Protocol_11Feb14.pdf(417.97 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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe risk factors for first discontinuation of cinacalcet among center-based hemodialysis patients,To describe factors with reinitiation of cinacalcet among center-based hemiodialysis patients,To describe the trajectory of parathyroid hormone, calcium, and phosphorus laboratory values following the discontinuation of cinacalcet by center-based hemodialysis patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Sensipar

Medical condition to be studied

Hyperparathyroidism secondary

Population studied

Short description of the study population

Adult patients (18 years and older) with end-stage renal disease (ESRD) who received center based hemodialysis at a DaVita facility in the United States and had Medicare as their primary insurer between 2006 and 2010.

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

44000

Study design details

Outcomes

Probability of first cinacalcet discontinuation.Probability of cinacalcet reinitiation follwoing the first discontinuation of period.Mean values of parathyroid hormone, calcium and phosphorus.

Data analysis plan

Logistic regression will be used to estimate the probability of reinitiating or not reinitiating cinacalcet given the various convariates determined at the end of the previous 30-day interval and identify predicators of discontinuation and reinitiation. Laboratory values following of discontinuation as a function of time will be modeled using smoothing splines.

Documents

Study results

Cinacalcet_Discontinuation_20130335_ORSR_20Mar2015.pdf(1.15 MB)

Data management

Data sources

Data source(s), other

United States Renal Data System (USRDS) including Medicare Part D prescription claims 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