A Multi-country Prospective Observational Study to Describe Calcimimetic Use in Haemodialysis Patients

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48608

EU PAS number

EUPAS18923

Study ID

48608

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Belgium
- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Israel
- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Russian Federation
- [ ] Spain
- [ ] United Kingdom

Study description

In Europe, two calcimimetics, cinacalcet (Mimpara®) and etelcalcetide (Parsibiv®) are approved for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD). Mimpara is approved for patients treated with maintenance dialysis, whilst etelcalcetide has been approved for patients specifically receiving haemodialysis (HD) therapy. Oral cinacalcet was the first calcimimetic to be approved by the European Medicines Agency (EMA) that was granted marketing authorization in 2004. An intravenous (i.v.) calcimimetic, etelcalcetide, received marketing authorisation from the EMA in November 2016. Data from clinical trials and real-life clinical practice have demonstrated the effectiveness of cinacalcet in reducing PTH levels. 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, there is a lack of real-world

data describing achievement of PTH control and medication persistence of etelcalcetide. This observational study will describe parameters of drug utilisation of both etelcalcetide and cinacalcet in a contemporary real world clinical setting.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Multiple centres: 120 centres are involved in the study

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: 07/11/2016

Study start date

Planned: 11/12/2017

Actual: 07/06/2018

Data analysis start date

Planned: 22/12/2021

Actual: 10/03/2022

Date of final study report

Planned: 22/06/2022

Actual: 16/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20150297 Abstract.pdf(117.08 KB)

01.02.06 Public Redacted Protocol Ver 1.0 2020-03-06 English.pdf(365.12 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

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To describe the proportion of patients discontinuing treatment at 3-monthly interval up to 18 months following treatment initiation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

PARSABIV

MIMPARA

Anatomical Therapeutic Chemical (ATC) code

(H05BX04) etelcalcetide

etelcalcetide

(H05BX01) cinacalcet

cinacalcet

Medical condition to be studied

Chronic kidney disease

Population studied

Short description of the study population

Patients aged 18 years or older with chronic kidney disease (CKD) receiving hemodalysis therapy (HD) initiated calcimimetic (ie, calcimimetic naïve cinacalcet patients) or etelcalcetide (etelcalcetide patients with or without a history of prior cinacalcet use) treatment after February 2017, outside a clinical trial setting.

Inclusion criteria:

• Aged ≥ 18 years and receiving HD for end-stage renal disease (ESRD) at time of calcimimetic initiation

• Patients initiating calcimimetic between date of site-specific etelcalcetide access (eg, known date of first drug order or date of first drug administration at site) to 30 November 2019 or date of site evaluation (ie, evaluation of site for study participation), whichever occurs last, are eligible, specifically:

a) Calcimimetic naïve cinacalcet patients with at least one prescription for cinacalcet; or

b) Etelcalcetide patients with or without a history of prior cinacalcet use and received at least one dose administration of etelcalcetide

• Provided informed consent or notified of participation, according to local laws and regulations requirements

Exclusion criteria:

• No PTH measurement within 90 days prior to calcimimetic initiation

• Participated in a clinical trial of calcimimetic ≤ 90 days of initiating calcimimetic treatment
• Previously participated in an expanded access program for etelcalcetide

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

1600

Study design details

Outcomes

Proportion of patients discontinuing treatment of calcimimetic at 3-month intervals up to 18 months following calcimimetic initiation, Demographics, clinical characteristics, dialysis parameters, laboratory parameters, calcimimetic use, concomitant sPTH therapy use, events of interest and hypocalcemia incidence

Data analysis plan

Analyses will be descriptive. For continuous variables, descriptive statistics, for example, mean, standard deviation (SD), standard error (ER), median, interquartile range (25th and 75th percentile), minimum, and maximum values

will be presented. For categorical variables, the number and percentage of participants in each category will be reported with 95% two-sided confidence intervals (CIs). Variables measured longitudinally (e.g. PTH, Ca and P prior to and after calcimimetic initiation) will also be summarized graphically by plotting the mean (+/- SE) against time.

Documents

Study results

20150297_ORSR_abstract_Redacted ENCEPP.pdf(309.2 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Chart Review

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