A Prospective Cohort Study to Describe Use and Safety of Cinacalcet in Pediatric Patients Receiving Dialysis in the NAPRTCS Registry (20120116)

First published: 11/02/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17576

EU PAS number

EUPAS5647

Study ID

17576

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] Costa Rica
- [ ] Mexico
- [ ] United States

Study description

Describe the demographics, laboratory values, and secondary hyperparathyroidism (SHPT) medication use (specifically cinacalcet), and the occurrence of hypocalcemia, seizures, and infections (requiring hospitalization), in cinacalcet treated and untreated patients enrolled in the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) receiving dialysis for chronic kidney disease (CKD).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

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Institution

North American Pediatric Renal Trials and Collaborative Studies Boston, MA, USA

Contact details

Study institution contact

Global Development Leader Amgen, Inc

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: 22/06/2012

Study start date

Actual: 01/08/2012

Data analysis start date

Actual: 01/08/2013

Date of interim report, if expected

Actual: 01/10/2013

Date of final study report
Planned: 22/07/2016

Actual: 31/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Cinacalcet_20120116_Protocol_11Feb14.pdf(284.36 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Describe the demographics, laboratory values, and secondary hyperparathyroidism (SHPT) medication use (specifically cinacalcet), and the occurrence of hypocalcemia, seizures, and infections (requiring hospitalization), in cinacalcet treated and untreated patients enrolled in the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) receiving dialysis for chronic kidney disease.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Sensipar

Medical condition to be studied

Central hypothyroidism

Population studied

Short description of the study population

All patients < 21 years of age receiving maintenance dialysis for chronic kidney disease (CKD) at a North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) affiliated center, and who were enrolled in the registry.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Renal impaired

Estimated number of subjects

1000

Study design details

Outcomes

Demographic characteristics, laboratory values (PTH, calcium, phosphorus), SHPT medication use, occurrence of clinical events (hypocalcemia, seizures, infections requiring hospitalization).

Data analysis plan

The analyses will describe the study population and outcomes as follows: 1) total number of patients and total number of patient-years observation based on the annual data reporting periods, and for the cumulative 3-year study period, 2)estimation of rates of cinacalcet use based on the annual data reporting periods, andfor the cumulative 3-year study period, 3) estimation of rates of AESI based on the annual data reporting periods, and for the cumulative 3-year study period, 4)proportion of patients who received at least 1 dose of cinacalcet within 7 days preceding an episode of hypocalcemia (from amongst all patients who developed hypocalcemia). Descriptive analyses using summary statistics will also be conducted to tabulate baseline demographic and clinical characteristics by cinacalcet-exposed and cinacalcet unexposed. The cinacalcet utilization pattern will also be assessed (eg, dosing, duration of treatment).

Documents

Study results

20120116_ORSR_Abstract.pdf(14.16 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown