An Observational Registry Study To Evaluate The Use And Safety Of Cinacalcet Among Paediatric Patients With Secondary Hyperparathyroidism (20180204)

First published: 16/08/2018

Last updated: 07/11/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38179

EU PAS number

EUPAS24954

Study ID

38179

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

Study description

This is a non-interventional observational registry of paediatric patients receiving maintenance dialysis with sHPT and using cinacalcet. A patient will receive standard of care treatment as determined by the patient’s physician.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Bordeaux University Hospital (CHU de Bordeaux)

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

University Medical Centre Hamburg-Eppendorf

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Motol University Hospital (FNM)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Heidelberg University Hospital

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Institution

- Universitair Ziekenhuis Gent (Ghent University Hospital)
- Universitaetsklinikum Allgemeines Krankenhaus Wien (Vienna General Hospital)
- Universitair Ziekenhuis Leuven (UZ Leuven) - Campus Gasthuisberg
- Hopital Universitaire des Enfants Reine Fabiola (Queen Fabiola Children's University Hospital)
- Universite Catholique de Louvain, Cliniques Universitaires Saint Luc
- Clinique Centre Hospitalier Chrétien MontLégia
- Hospices Civils de Lyon
- Hopital Femme Mere Enfant
- Hopital des Enfants Centre
- Hospitalier Regional Universitaire de Montpellier

- Hopital Arnaud de Villeneuve
- Hopital Pellegrin
- Centre Hospitalier Universitaire Archet 2
- Kindernierenzentrum Bonn
- Medizinische Hochschule Hannover
- Charite – Universitaetsmedizin Berlin, Campus Virchow
- General Children Hospital Panagioti and Aglaias Kyriakou
- Ippokrateio General Hospital of Thessaloniki
- IRCCS Istituto Giannina Gaslini
- IRCCS Ospedale Pediatrico Bambino Gesu
- Unidade Local de Saude de Sao Jose, EPE
- Hospital Universitari Vall d Hebron
- Royal Hospital for Children Glasgow
- Southampton Children's Hospital
- Royal Manchester Children's Hospital

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

Planned: 01/04/2019

Actual: 13/06/2018

Study start date

Planned: 20/01/2020

Actual: 09/01/2020

Data analysis start date

Planned: 09/05/2024

Actual: 09/05/2024

Date of interim report, if expected

Planned: 14/11/2022

Actual: 30/03/2023

Date of final study report

Planned: 31/12/2024

Actual: 07/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 English.pdf(1.03 MB)

Protocol-Published Amendment cinacalcet hydrochloride 20180204 8.pdf(1.12 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

20180204

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To describe patient characteristics, how cinacalcet is used, laboratory values over time, the incidence of hypocalcaemia, risk factors associated with time to hypocalcaemia event and management of hypocalcaemia in paediatric patients with secondary hyperparathyroidism (sHPT).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective and prospective chart review study

Study drug and medical condition

Name of medicine

MIMPARA

Study drug International non-proprietary name (INN) or common name

CINACALCET

Anatomical Therapeutic Chemical (ATC) code

(H05BX01) cinacalcet

cinacalcet

Medical condition to be studied

Hypocalcaemia

Hyperparathyroidism secondary

Population studied

Short description of the study population

The registry will enrol eligible paediatric patients on maintenance dialysis who are prescribed cinacalcet treatment.

Age groups

Paediatric Population (< 18 years)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

45

Study design details

Outcomes

In a European cohort of paediatric patients with sHPT on maintenance dialysis and using cinacalcet: To describe the patient characteristics, how cinacalcet is used, the laboratory values (PTH, cCa, phosphate and albumin) over time and the incidence, management and risk factors associated with hypocalcaemia.

Data analysis plan

There are no formal hypotheses for the study. Descriptive data analyses will be performed. Characteristics of patients who develop and do not develop hypocalcaemia will be described. Treatment characteristics (cinacalcet and other sHPT medications) will be summarised prior to cinacalcet initiation and after a hypocalcaemia event. PTH, cCa, phosphate and albumin laboratory parameters over time will be summarised. To describe time-to-event of first hypocalcaemia event, cinacalcet discontinuation and cinacalcet re-initiation, Kaplan-Meier (KM) curves will be calculated.

Documents

Study report

20180204_ORSR Abstract_21OCT2024_Redacted.pdf(1.35 MB)

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Routine primary care electronic patient registry

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