Cinacalcet Use and the Risk of Gastrointestinal (GI) Bleeding Among Hemodialysis Patients with Secondary Hyperparathyroidism (SHPT) in DOPPS

First published: 09/04/2018

Last updated: 26/06/2019

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30274

EU PAS number

EUPAS23268

Study ID

30274

DARWIN EU® study

No

Study countries

United States

Study description

The rate of GI bleeding in the 2013 US Medicare hemodialysis population was 23 per 1,000 patien-years (PYs), while the mortality rate from GI bleeding was 0.91 per 1,000 PYs. In placebo-controlled trials, the rate of GI bleeding in hemodialysis patients was similar in the etelcalcetide group (2.0%) and the placebo group (2.1%). We will conduct an observational study to address the possibility of a potential association between calcimimetics and fatal and non-fatal GI bleeding in a population of hemodialysis patients.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

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: 26/10/2017

Actual: 14/03/2018

Study start date

Planned: 01/05/2018

Actual: 01/05/2018

Data analysis start date

Planned: 01/09/2018

Actual: 01/09/2018

Date of final study report

Planned: 30/06/2019

Actual: 24/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen, Inc.

Study protocol

EUPAS23268-23566.pdf(433.84 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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

1: Estimate the association between exposure to cinacalcet and the risk of hospitalization from GI bleeding, by region and overall.2. Estimate the association between exposure to cinacalcet and the risk of death from GI bleeding, by region and overall.3: Estimate the rate of hospitalization from GI bleeding and the rate of death from GI bleeding, by region and overall.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

MIMPARA

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

CINACALCET HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(H05BX01) cinacalcet

cinacalcet

Medical condition to be studied

Gastrointestinal haemorrhage

Population studied

Short description of the study population

Patients aged ≥18 years who had received in-center hemodialysis at a Dialysis Outcomes and Practice Patterns Study (DOPPS) facility.

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

10000

Study design details

Outcomes

GI bleeding in a hospital setting and death from GI bleeding

Data analysis plan

Descriptive statistics using mean and standard deviation (SD) or median and 25th/75th percentile estimates for continuous variables (as appropriate) and number and percentages (n, %) for categorical variables will be used to examine patient characteristics in a cohort of subjects with SHPT who are on dialysis.We will estimate the hazard ratio (HR) and 95% CI for the association of cinacalcet exposure and risk of an inpatient hospitalization for GI bleeding (or death from GI bleeding), implemented using conditional logistic regression analysis for standard matched case-control studies.We will estimate the crude incidence rates of hospitalization for GI bleeding or crude death rates from GI bleeding and associated 95% CIs using the Poisson model.

Documents

Study results

20170665_Observational Research Study Report - Cinacalcet Use and the Risk of Gastrointestinal Bleeding abstract.pdf(154.41 KB)

Data management

Data sources

Data sources (types)

Disease 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