An Observational Study to Evaluate the Potential Association Between ParsabivTM and Gastrointestinal Bleeding (20170561)

First published: 20/03/2018

Last updated: 23/09/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50484

EU PAS number

EUPAS23186

Study ID

50484

DARWIN EU® study

No

Study countries

☐ United States

Study description

The Food and Drug Administration (FDA) required Amgen to conduct an observational study to assess the potential association between ParsabivTM (etelcalcetide) and fatal and non-fatal gastrointestinal bleeding as a post-marketing requirement. This observational study is designed to assess the potential association between ParsabivTM use and the risk of fatal and non-fatal GI bleeding in patients receiving maintenance hemodialysis, using a nested case control study design.

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

Actual: 28/02/2018

Study start date

Planned: 01/07/2018

Actual: 01/07/2018

Data analysis start date

Planned: 01/05/2022

Actual: 01/05/2022

Date of final study report

Planned: 31/12/2022

Actual: 28/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Amendment etelcalcetide 20170561 2 .pdf(1.76 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)

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

Data collection methods:

Secondary use of data

Main study objective:

To assess the potential association between ParsabivTM use and risk of gastrointestinal bleeding in secondary hyperparathyroidism (HPT) patients receiving maintenance hemodialysis

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Nested, matched case-control study

Study drug and medical condition

Name of medicine

PARSABIV

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

ETELCALCETIDE HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(H05BX04) etelcalcetide

etelcalcetide

Medical condition to be studied

Gastrointestinal haemorrhage

Population studied

Short description of the study population

Patients with secondary hyperparathyroidism (HPT) receiving maintenance hemodialysis (HD) aged 18 years or more identified from DaVita-Medicare linked database between 2018 and 2020.

Inclusion criteria:

- age ≥ 18 years
- at least 91 days on HD
- covered by Medicare Parts A, B, and D for at least 365 days
- received HD for at least 91 days at a DaVita dialysis facility
- parathyroid hormone > 300 pg/mL during the baseline period (365 days before the cohort entry date)
- no etelcalcetide use for 365 days (baseline period)
- no GI-bleeding event for 365 days (baseline period)

Exclusion criteria:

- history of parathyroidectomy
- previous kidney transplant

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

Other

Renal impaired

Special population of interest, other

Patients with secondary hyperparathyroidism

Estimated number of subjects

40000

Study design details

Outcomes

The composite event of fatal and non-fatal GI bleeding. A fatal GI bleeding will be defined as death with GI bleeding as a cause and a non-fatal GI bleeding event will be defined as a hospitalization with GI bleeding as the primary diagnosis

Data analysis plan

Descriptive statistics will be used to compare cases and controls, with respect to demographic, comorbidity and medication use characteristics. The odds of exposure among case and controls will be calculated. Conditional logistic regression will be used to estimate the OR and the associated 95% confidence interval (CI) for the association between ParsabivTM use (reference = no ParsabivTM use) and risk of fatal and non-fatal GI bleeding adjusting for other

potential confounders. If the upper limit of the 95% confidence interval of the estimated OR is less than 1.30, the conclusion will be that ParsabivTM use is associated with a less than 30% increased relative risk of fatal or non fatal GI bleeding.

Documents

Study results

20170561 ORSR_Redacted.pdf(105.72 KB)

Data management

Data sources

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