

# An Observational Study to Evaluate the Potential Association Between Parsabiv™ 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>

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### EU PAS number

EUPAS23186

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### Study ID

50484

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### DARWIN EU® study

No

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### Study countries

United States

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## Study description

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

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## 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](mailto: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

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### **Study start date**

Planned: 01/07/2018

Actual: 01/07/2018

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### **Data analysis start date**

Planned: 01/05/2022

Actual: 01/05/2022

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### **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

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### **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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

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

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Nested, matched case-control study

## Study drug and medical condition

**Name of medicine**

PARSABIV

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

Etelcalcetide Hydrochloride

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## **Anatomical Therapeutic Chemical (ATC) code**

(H05BX04) etelcalcetide

etelcalcetide

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## **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  $\geq$  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
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### **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)

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### **Special population of interest**

Other  
Renal impaired

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### **Special population of interest, other**

Patients with secondary hyperparathyroidism

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### **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

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### **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 Parsabiv™ use (reference = no Parsabiv™ 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 Parsabiv™ 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)

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## 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No