

# Romiplostim effectiveness stratified on duration of immune thrombocytopenia at initiation

**First published:** 16/11/2019

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32183

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### Study ID

36382

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Research institutions and networks

## Institutions

### Amgen

 United States

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Institution

NoviSci, Inc. United States

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

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**

Planned: 22/01/2019

Actual: 22/01/2019

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**Study start date**

Planned: 01/11/2019

Actual: 17/10/2019

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**Data analysis start date**

Planned: 17/10/2019

Actual: 17/10/2019

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**Date of final study report**

Planned: 12/06/2020

Actual: 16/07/2020

## 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 2019-11-19 English.pdf \(297.16 KB\)](#)

## Regulatory

**Was the study required by a regulatory body?**

No

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Among patients who received romiplostim in routine care in one of seven countries (Austria, Belgium, Czech Republic, France, Greece, Portugal and Sweden), describe the following overall and within strata of duration of ITP: patient profile at romiplostim initiation, patterns of romiplostim use and overall platelet count trends, effectiveness of romiplostim via platelet-based and other endpoints.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Secondary analysis of data collected through a European, multi-center, observational cohort study (Amgen Study 20070225)

## Study drug and medical condition

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

ROMIPLOSTIM

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### **Medical condition to be studied**

Immune thrombocytopenia

## Population studied

### **Short description of the study population**

The previously conducted cohort study (Amgen Study 20070225) enrolled 340 eligible participants. Patients were  $\geq 18$  years old, diagnosed with primary ITP, and had received at least one dose of romiplostim. Exclusion criteria included receipt (or planned receipt) of platelet related products (eg, recombinant human thrombopoietin [rHuTPO], thrombopoietin receptor agonists, pegylated recombinant human megakaryocyte growth and development factor [PEG-rHuMGDF]), participation in any interventional clinical study, or initiation of romiplostim prior to commercial availability of the product

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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

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

Immune thrombocytopenic purpura patients

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### **Estimated number of subjects**

340

## **Study design details**

### **Outcomes**

Durable platelet response, median overall platelet count, overall platelet response, time to first platelet response, Discontinuation of concurrent medications, bleeding, splenectomy, adverse drug reaction, thrombotic events, bone marrow fibrosis

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### **Data analysis plan**

Descriptive statistics of the clinical and demographic characteristics of the cohort will be provided, as will patterns of romiplostim use and platelet count trends. Estimates of medians, proportions, probabilities, and rates will be calculated for the endpoints of interest and presented with appropriate measures of variability. No hypotheses will be tested.

## Documents

### **Study results**

[20190407\\_Observational Research Study Report Published Report\\_Redacted.pdf](#) (149.37 KB)

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## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

## **Data sources (types)**

Other

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### **Data sources (types), other**

Completed retrospective chart review in European clinical practices

## 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