

# A cross-sectional study of patients with immune thrombocytopenic purpura and caregivers to estimate the proportion who administer romiplostim correctly after receipt of home administration training materials (20120269)

**First published:** 07/07/2014

**Last updated:** 05/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6658

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### Study ID

20208

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### DARWIN EU® study

No

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### Study countries

-  Austria
  -  Belgium
  -  France
  -  Germany
  -  Greece
  -  Netherlands
  -  Spain
  -  United Kingdom
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## **Study description**

The objective of this study is to estimate the proportion of subjects and caregivers who administer romiplostim correctly after being trained with the home administration training pack. This is a cross-sectional study with direct observation made by healthcare professionals of subjects or caregivers, administering romiplostim at their first standard-of-care visit 4 weeks after training. Further observations can also be recorded in the study if made within 16 weeks of enrolment. Data will be collected from the subjects' dose diary at their first standard of care visit to ensure there were no problems with administration while not at the clinic.

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## **Study status**

Finalised

## Research institutions and networks

### Institutions

**Amgen**



United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

**Institution**

## 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

Actual: 13/12/2013

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### Study start date

Planned: 04/08/2014

Actual: 07/07/2014

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### Data analysis start date

Planned: 07/03/2016

Actual: 03/02/2016

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### **Date of final study report**

Planned: 12/04/2016

Actual: 12/05/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## 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:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of this study is to estimate the proportion of adult subjects and caregivers who correctly administer romiplostim after being trained with the home administration training pack.

## Study Design

**Non-interventional study design**

Cross-sectional

## 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**

## Population studied

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

Adult Immune thrombocytopenic purpura (ITP) patient, treated per EU SmPC, or caregiver new (or at least a 3-month gap) to romiplostim administration; who had received Home Administration Training (HAT) pack training and were available at standard-of-care medical visit 4 weeks (range 2 to 8 weeks) after HAT pack training; and provided informed consent.

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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**

Immunocompromised

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### **Estimated number of subjects**

40

## Study design details

### **Outcomes**

Successful self administration of romiplostim Time Frame: First Standard of Care visit post Home Administration Training (range 2-8 weeks) , Successful reconstitution of romiplostim Accuracy in administering the prescribed dose of romiplostim Successful injection of romiplostim Successful self administration of romiplostim at follow up visits

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### **Data analysis plan**

The primary endpoint is a categorical yes/no indicator for whether the subject or caregiver administers romiplostim correctly at the 4 week visit. It is a composite endpoint based on a number of criteria and will be "yes" if all are met, and "no" if any of the criteria are not met. The data analysis for this study will be descriptive in nature. Endpoints/variables of a binary nature, such as the primary endpoint, will be summarized as the frequency and proportion (percentage). As a measure of precision, a 95% confidence interval (binomial exact) will be calculated around the point estimate (proportion).

Endpoints/variables of a continuous nature will be summarized using the mean, standard deviation, range and median. The target sample size is 40 subjects.

With this sample size, the 95% confidence interval around an observed proportion of 90% of subjects or caregivers correctly administering romiplostim is 77% to 96%.

## Documents

### **Study results**

[01.09.01 Clinical Study Report 2016-04-04 20120269 Final report \(abstract, pages 8-11\).pdf](#) (44 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

Prospective patient-based data collection

## 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**

Unknown