

# Primary Immune Thrombocytopenia Treated with Romiplostim (20140451)

**First published:** 08/10/2015

**Last updated:** 03/02/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11186

### Study ID

17010

### DARWIN EU® study

No

### Study countries

☐ United Kingdom

### Study status

Finalised

## Research institutions and networks

# Institutions

## Amgen

☐ United States

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

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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: 11/07/2014

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**Study start date**

Actual: 18/09/2015

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**Data analysis start date**

Planned: 22/01/2016

Actual: 22/01/2016

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**Date of final study report**

Planned: 31/12/2016

Actual: 03/01/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol-Published Original romiplostim 20140451.pdf](#) (564.01 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)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

**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:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

- Describe the demographic and clinical characteristics of patient who have received romiplostim at the time of romiplostim initiation.
- Describe ITP medication use since diagnosis and platelet counts prior to and post-romiplostim initiation in the study population.

## Study Design

**Non-interventional study design**

Cohort

## 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

Adult patients within the United Kingdom Immune Thrombocytopenia (UKITP) Registry diagnosed with primary Immune Thrombocytopenia (ITP) and who had received at least 1 dose of romiplostim after launch in the United Kingdom in October 2009.

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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

130

## Study design details

## Outcomes

Demographic (sex, age, ethnicity) and clinical characteristics (specific comorbidities, diagnosis details) will be described using descriptive statistics. ITP therapies since diagnosis will be described and platelet counts at romiplostim initiation and after will be summarised.

The pattern of romiplostim administration will be described. Rate of bleeding events, hospitalisations and use of rescue medications will also be described

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## Data analysis plan

The data analysis for this study will be descriptive in nature.

Endpoints/variables of a binary nature, will be summarised as a proportion.

Endpoints/variables of a continuous nature will be summarized using the mean, standard deviation, median and interquartile range, minimum and maximum value.

For measuring rate of events of interest in person-time, the number of events during the time at risk will be divided by the total person-time at risk. 95% confidence interval (Poisson) will be generated for each estimate.

## Documents

### Study results

[01.09.01 Clinical Study Report 2016-12-14 20140451 Final report\\_abstract \(pages 8-11\).pdf](#) (50.57 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 source(s), other

United Kingdom Immune Thrombocytopenia (UKITP) Registry United Kingdom

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### Data sources (types)

[Disease registry](#)

## 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