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

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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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: 11/07/2014

Study start date
Actual: 18/09/2015

Data analysis start date
Planned: 22/01/2016

Actual: 22/01/2016

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

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

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.

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

Special population of interest, other

Immune thrombocytopenic purpura patients

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 thetime 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)

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

Data sources (types)

Disease registry

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

Unknown