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

PURI

https://redirect.ema.europa.eu/resource/20208

EU PAS number

EUPAS6658

Study ID

20208

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

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.

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

Primary lead investigator

Global Development Leader Amgen, Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/12/2013

Study start date

Planned: 04/08/2014

Actual: 07/07/2014

Data analysis start date
Planned: 07/03/2016

Actual: 03/02/2016

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

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to estimate the proportion of adult subjects and caregivers who correctly adminster 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

Medical condition to be studied

Immune thrombocytopenia

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.

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

Immunocompromised

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 romiplostimAccuracy in administering the prescribed dose of romiplostimSuccessful injection of romiplostimSuccessful self administration of romiplostim at follow up visits

---

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)

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown