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

Study ID

36382

DARWIN EU® study

No

Study countries

☐ United States

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

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Study contact

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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

Study start date
Planned: 01/11/2019

Actual: 17/10/2019

Data analysis start date
Planned: 17/10/2019

Actual: 17/10/2019

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

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

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

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 ≥ 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)

Special population of interest

Other

Special population of interest, other

Immune thrombocytopenic purpura patients

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

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)

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No