

Targeted Literature Review to Describe Safety Outcomes in Immune Thrombocytopenia Patients Treated With Thrombopoietin-Receptor Agonists

First published: 04/11/2019

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/35906>

EU PAS number

EUPAS32139

Study ID

35906

DARWIN EU® study

No

Study countries

United States

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.

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: 04/09/2019

Study start date

Planned: 26/10/2019

Actual: 26/10/2019

Data analysis start date

Planned: 15/11/2019

Actual: 15/11/2019

Date of final study report

Planned: 15/05/2020

Actual: 19/06/2020

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 2019-10-15 English.pdf\(362.2 KB\)](#)

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

1. To estimate the incidence of bone marrow fibrosis/reticulin formation in adults with immune thrombocytopenia (ITP) who have been treated with

romiplostim therapy, other Thrombopoietin-Receptor Agonists (TPO-RAs), and other ITP therapies.² To estimate the incidence of hematologic malignancy in adults with ITP who have been treated with each of the therapies listed above.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medical condition to be studied

Immune thrombocytopenia

Population studied

Short description of the study population

Studies that include information on treated adult Immune Thrombocytopenia Patients (ITP) patients from all countries/regions will be included.

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 Thrombocytopenia Patients

Estimated number of subjects

0

Study design details

Outcomes

bone marrow fibrosis/reticulin formation, hematologic malignancy, thrombotic/thromboembolic events, pre-malignant stages (acute myelogenous leukemia and myelodysplastic syndromes), leukocytosis, anemia, acute renal failure

Data analysis plan

A narrative synthesis of the studies included in the systematic literature review will be presented that will describe the overall strength of the collective evidence to address the research questions. If sufficient data are available for a given study outcome (e.g. incidence of bone marrow fibrosis among adult ITP patients treated with romiplostim) from the literature review, the data may be quantitatively summarized using a meta-analysis. Sufficient data is defined as at least 3 studies within each patient group (romiplostim, other TPO-RAs, or specific therapies within the other ITP therapies group) using the same outcome definition.

Documents

Study results

[SLR Executive Summary 2020-05-23.pdf](#)(96.25 KB)

Data management

Data sources

Data sources (types)

[Published literature](#)

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