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

First published: 04/11/2019

Last updated: 23/04/2024

Study Finalised

Administrative details

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.

medinfo@amgen.com

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

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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

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 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