Effectiveness of the Nplate Additional Risk Minimisation Materials Implemented in Australia (20210176)

First published: 31/03/2022

Last updated: 08/03/2023

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49211

EU PAS number

EUPAS46340

Study ID

49211

DARWIN EU® study

No

Study countries

☐ Australia

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
Planned: 01/04/2022

Actual: 01/04/2022

Study start date
Planned: 01/04/2022

Actual: 06/04/2022

Data analysis start date
Planned: 01/06/2022

Actual: 01/06/2022

Date of final study report
Planned: 30/11/2022

Actual: 25/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original romiplostim 20210176.pdf(2.98 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To assess whether the aRMMs implemented by Amgen Australia are effective in minimizing the risk of medication errors in patients being treated with NPlate by

determining usage and utility of the aRMMS and if the incidence of medication errors in Australia has changed.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Online survey

Study drug and medical condition

Name of medicine

NPLATE

Medical condition to be studied

Thrombocytopenia

Population studied

Short description of the study population

An online survey of haematologists and haematology nurses who had treated patients with immune thrombocytopenia (ITP) with Nplate for the period of 12 December 2018 to 31 December 2021.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

30

Study design details

Data analysis plan

This study is analyzing secondary data from the Amgen drug safety database and no safety data will be collected.

Documents

Study results

20210176_ORSR_Abstract_Redacted.pdf(269.81 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Questionnaire for healthcare providers and safety data analysis of data from Amgen drug safety database

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