Longitudinal study on the epidemiology and management of auto-immune thrombocytopenia (AITP) in Algeria

First published: 08/09/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36269

EU PAS number

EUPAS20687

Study ID

36269

DARWIN EU® study

No

Study countries

☐ Algeria

Study description

Epidemiological, national, prospective, longitudinal study about the management of patients with auto-immune thrombocytopenia followed up by hematologists in the public sector in Algeria.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 16 centres are involved in the study

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: 07/04/2017

Actual: 07/07/2017

Study start date

Planned: 08/09/2017

Actual: 08/09/2017

Data analysis start date

Planned: 31/07/2019

Actual: 14/07/2019

Date of final study report

Planned: 30/06/2020

Actual: 09/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160214_01.02.06 Public Redacted Protocol Ver 1.0 2018-07-28 English.pdf
(557.28 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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess the incidence of AITP diagnosed in patients aged 16 years old and over in Algeria in a 12-month period of inclusion

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal prospective epidemiological study

Study drug and medical condition

Medical condition to be studied

Immune thrombocytopenia

Population studied

Short description of the study population

All patients over 16 years old previously diagnosed (prior to inclusion visit) or newly diagnosed (at the time of the inclusion visit) with AITP, treated in the hematology departments in Algeria and who gave their informed consent, were included in the study.

Age groups

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)

Special population of interest

Other

Special population of interest, other

Immune thrombocytopenic purpura patients

Estimated number of subjects

200

Study design details

Outcomes

Number of new cases diagnosed with AITP and aged 16 years and over, in Algeria during the period of 12 months of inclusion. Number of new cases diagnosed with AITP and aged 16 years and over, during the period of 12

months of inclusion, by age categories. Number diagnosed with AITP and aged 16 years and over, in Algeria during the period of 12 months of inclusion, by gender, diagnosis stage, Wilaya.

Data analysis plan

This study is an estimation study, so no formal statistical testing will be performed. A descriptive analysis of the collected variables will be conducted.

Documents

Study results

20160214_AITP_CSR_24JULY2019_Final (002)_Redacted.pdf(261.64 KB)

Data management

Data sources

Data sources (types)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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