

# 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>

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### EU PAS number

EUPAS20687

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### Study ID

36269

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### DARWIN EU® study

No

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### Study countries

Algeria

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## 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.

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## 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](mailto: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

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**Study start date**

Planned: 08/09/2017

Actual: 08/09/2017

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**Data analysis start date**

Planned: 31/07/2019

Actual: 14/07/2019

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**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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Combined primary data collection and secondary use of data

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**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

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**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.

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### **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)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Immune thrombocytopenic purpura patients

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### **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.

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### **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\(261.64 KB\)](#)

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## Data management

### Data sources

#### **Data sources (types)**

[Disease registry](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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#### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No