# 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

**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:** 27/03/2026

**Institution**

### Multiple centres: 16 centres are involved in the study

# 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**

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

**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

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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.

**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

## 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)**

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