

# Use of Bone Marrow Biopsies in Patients With Chronic Immune Thrombocytopenia: Predictors For, And Prognosis After – a Nordic Population-based Cohort Study And a Nested Case Control Study

**First published:** 28/02/2020

**Last updated:** 08/02/2021

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/39431>

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### **EU PAS number**

EUPAS33657

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### **Study ID**

39431

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### **DARWIN EU® study**

No

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### Study countries

- Denmark
  - Norway
  - Sweden
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### Study description

The study will characterize patients with chronic immune thrombocytopenia, including prevalence and incidence of biopsies, risk factors associated with biopsies, and outcomes among these patients.

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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**

#### Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

- Denmark

**First published:** 20/07/2021

**Last updated:** 02/04/2024

**Institution**

**Educational Institution**

**ENCePP partner**

## Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## 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: 12/09/2019

Actual: 12/09/2019

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**Study start date**

Planned: 25/02/2020

Actual: 25/02/2020

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**Data analysis start date**

Planned: 26/02/2020

Actual: 26/02/2020

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**Date of final study report**

Planned: 30/07/2020

Actual: 08/02/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen, Ltd

## Study protocol

[01.02.06 Public Redacted Protocol Ver 1.0 2020-02-21 English.pdf\(194.78 KB\)](#)

## 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:**

Secondary use of data

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#### **Main study objective:**

The objective of the study is to characterize patients with chronic immune thrombocytopenia who have had bone marrow biopsies.

## Study Design

## **Non-interventional study design**

Cohort

Case-control

## Study drug and medical condition

### **Medical condition to be studied**

Thrombocytopenia

## Population studied

### **Short description of the study population**

All adults ( $\geq 18$  years) with two or more ITP diagnoses registered at least 6 months apart from 1 January 1996 to 31 December 2017.

Exclusion criteria:

- o A diagnosis consistent with secondary ITP within 5 years before the date of cITP
  - o No recorded platelet count below  $150 \times 10^9/L$  according to the medical record
  - o A secondary cause of thrombocytopenia stated in the medical record.
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### **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)

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## Special population of interest

Other

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## Special population of interest, other

Immune thrombocytopenia Patients

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## Estimated number of subjects

500

# Study design details

## Outcomes

Incidence and prevalence of bone marrow biopsy among patients with chronic immune thrombocytopenia. Characteristics of patients with chronic immune thrombocytopenia who have had a bone marrow biopsy, and outcomes for patients with immune thrombocytopenia who have had a bone marrow biopsy.

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## Data analysis plan

Statistical analyses will be descriptive (incidence and prevalence) and exploratory (risk factors associated with biopsies as well as outcomes associated with bone marrow biopsies). The latter include hazard ratios for various outcomes.

# Documents

## Study results

[20190429 ORSR\\_Redacted.pdf](#)(137.61 KB)

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## Data management

## Data sources

## **Data sources (types)**

Disease registry

## 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