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





# Administrative details

EU PAS number		
EUPAS33657		
Study ID		
39431		
DARWIN EU® study		
No		
Study countries		
Denmark		
Norway		

Sweden			

#### **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.

### **Study status**

Finalised

# Research institutions and networks

# Institutions

Amgen
United States
First published: 01/02/2024
<b>Last updated:</b> 21/02/2024
Institution

# Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

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



### Contact details

Not-for-profit

### **Study institution contact**

Global Development Leader Amgen Inc. medinfo@amgen.com

**ENCePP** partner

 $\Big($  Study contact  $\Big)$ 

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

#### Study start date

Planned: 25/02/2020 Actual: 25/02/2020

### **Data analysis start date**

Planned: 26/02/2020 Actual: 26/02/2020

### **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
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:
Secondary use of data
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 (≥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  $150 \times 109/L$  according to the medical record o A secondary cause of thrombocytopenia stated in the medical record.

#### 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)

#### Special population of interest

Other

#### Special population of interest, other

Immune thrombocytopenia Patients

#### **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.

#### 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)

# 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

# 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