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

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

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

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 150×109/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

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