

The portuguese Survey on anTicoagulated pAtients RegisTer (START-Portugal-Register)

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Study

Ongoing

Administrative details

EU PAS number

EUPAS31461

Study ID

33725

DARWIN EU® study

No

Study countries

 Portugal

Study status

Ongoing

Research institutions and networks

Institutions

Association for Innovation and Biomedical Research on Light and Image (AIBILI)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Francisco Batel Marques

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/06/2019

Actual: 03/06/2019

Study start date

Planned: 20/01/2020

Actual: 27/01/2020

Date of interim report, if expected

Planned: 01/01/2021

Date of final study report

Planned: 01/07/2024

Sources of funding

- Other

More details on funding

AIBILI

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the START-Portugal-Register is to prospectively record the clinical history of adult patients receiving anticoagulant treatment for no more than 30 days, irrespectively of the prescribed drug and the indication for its use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Population studied

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

2000

Study design details

Outcomes

Major, minor and clinically relevant bleeding complications, Thrombotic events, Adverse events, Mortality (cardiovascular and total). Evaluation of the characteristics of the different available treatments (laboratory tests monitoring, frequency of control visits), Development of cancer, Organ failure.

Data analysis plan

A descriptive analysis will be conducted to all study variables. Categorical variables will be described through absolute and relative frequencies and continuous variables will be described by descriptive statistics using mean and standard deviation, quartiles, median value, minimum and maximum values. Univariate and multivariate analysis will be performed to evaluate the relationship between the presence of risk factors and the occurrence of events

of interest, including adverse events. A propensity score model will be applied to compare the safety and efficacy of the different anticoagulant treatments.

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

[Annex5_ Declaration Interests_signed.pdf](#) (721.25 KB)

Composition of steering group and observers

[START-Portugal-Register.pdf](#) (84.88 KB)

Data sources

Data sources (types)

[Other](#)

Data sources (types), other

Prospective patient-based data collection

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