Risks of pharmacological interactions of direct oral anticoagulants: thrombotic and hemorrhagic events leading to hospital admission in Catalonia. (IFACOD)

First published: 06/07/2022

Last updated: 09/04/2025

Study Planned

Administrative details

EU PAS number

EUPAS48017

Study ID

48018

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Riscos de les interaccions farmacològiques dels anticoagulants orals directes: esdeveniments trombòtics i hemorràgics que són motiu d'ingrés hospitalari a Catalunya.

Study status

Planned

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution **Educational Institution** **Laboratory/Research/Testing facility** **Not-for-profit** **ENCePP partner**

AQuAS, Agència de Qualitat i Avaluació Sanitàries de Catalunya

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 15/04/2022

Actual: 05/07/2022

Study start date

Planned: 01/09/2022

Data analysis start date

Planned: 01/01/2023

Actual: 30/06/2023

Date of final study report

Planned: 30/06/2025

Sources of funding

- Other

More details on funding

PADRIS, IDIAP

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:

Human medicinal product

Study topic, other:

Drug interactions

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To quantify the risk of the most relevant pharmacological interactions (pharmacokinetic or pharmacodynamic) with the Direct Oral Anticoagulants currently marketed in Catalonia and their clinical repercussions in the form of hemorrhagic or thrombotic events during 2014-2021.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Direct oral anticoagulants

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF) Direct factor Xa inhibitors

Direct factor Xa inhibitors

Medical condition to be studied

Atrial fibrillation

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

Hepatic impaired

Renal impaired

Estimated number of subjects

20000

Study design details

Outcomes

Risk of hemorrhage/thromboembolic event while on Direct Oral Anticoagulants compare to risk of hemorrhage /thromboembolic event while on Direct Oral Anticoagulants and an interacting drug.
Atrial fibrillation population adherence to Direct Oral Anticoagulants Risk of hemorrhage/ thromboembolic events in patients with good adherence to Direct Oral Anticoagulants

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Data analysis plan

Poisson conditional models will be used to estimate the incidence rate ratio (IRR) of primary and secondary events between the risk period (interaction) and the control period (non-interaction).
The models will be adjusted for confounding variables such as age, seasonality, comorbidity and other clinical or statistically relevant characteristics.

Data management

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

PADRIS Spain

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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