Impact of the COVID-19 pandemic in a cohort of anticoagulant users: a descriptive drug utilization study based on data from the Tuscany Healthcare administrative database

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Study Planned

Administrative details

EU PAS number

EUPAS37318

Study ID

37319

DARWIN EU® study

No

Study countries

☐ Italy

Study description

The rapid spread all over the world of the SARS-COV-2 forced all healthcare professionals to urgently reconsider the management of patients requiring continuing access to healthcare services such as patients treated with anticoagulants. Little is know on the impact of COVID-19 pandemic in the management of patients under anticoagulants treatment. Therefore, the aim of this study is to describe the use of anticoagulants in a large sample of the Italian population. For this purpose, electronic health records of Tuscany will be analyzed.

Study status

Planned

Research institutions and networks

Institutions

University of Milano Bicocca

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ippazio Cosimo Antonazzo

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/07/2020

Study start date
Planned: 01/10/2020

Date of final study report
Planned: 21/12/2020

Sources of funding

- Other

More details on funding

This is an independent study based on a spontaneous initiative of the participanting partners

Study protocol

PU_COVID_VKA_DOAC_full_protocol.pdf(252.3 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The aim of the study is to conduct a time-trend analysis in order to observe: 1. Possible changes in prevalence and incidence of VKAs and DOACs use potentially associated with COVID-19 pandemic2. Possible changes in the secular trends of switch from VKAs to DOACs potentially associated with COVID-19 pandemic

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

(B01AF03) edoxaban

edoxaban

(B01AA) Vitamin K antagonists

Vitamin K antagonists

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)

Estimated number of subjects

130000

Study design details

Outcomes

1) number of switchers during follow-up, 2) number of interrupters during follow-up

Data analysis plan

The prevalent/incident users, switchers and interrupters will be calculated on a weekly basis during the entire observation period (01/01/2019-30/06/2020). To evaluate the effect of COVID-19 pandemic prescribing patterns of VKAs/DOACs before and after the 9th of March 2020, which is the date of the official lockdown, an interrupted time series (ITS) analysis will be carried out.

Data management

Data sources

Data source(s)

ARS Toscana

Data source(s), other

ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

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