Drugs associated with Spontaneous Coronary Artery Dissection: a WHO pharmacovigilance database disproportionality analysis

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Study Ongoing

Administrative details

EU PAS number

EUPAS46697

Study ID

46698

DARWIN EU® study

No

Study countries

☐ France

Study status

Ongoing

Research institutions and networks

Institutions

Toulouse University Hospital

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Institution

Contact details

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Primary lead investigator

François Montastruc

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/04/2022

Actual: 07/04/2022

Study start date

Planned: 07/04/2022

Actual: 07/04/2022

Data analysis start date
Planned: 09/05/2022

Date of final study report
Planned: 29/07/2022

Sources of funding

- Other

More details on funding

Study not funded

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

Main study objective:

To estimate risk of SCAD for drugs of the database with at least 3 cases of SCAD

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-Non case study

Study drug and medical condition

Medical condition to be studied

Coronary artery dissection

Additional medical condition(s)

spontaneous coronary artery dissection (SCAD)

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

15000000

Study design details

Outcomes

RIsk of SCAD

Data analysis plan

Descriptive statistics will be used to compare characteristics between reports. Using a case/non-case design, we will estimate ROR for each drug of interest. Moreover, we will conduct sensitivity analyses to assess the robustness of the signals. We will restrict analysis to reports declared by a healthcare physician. To take in account the potential confusion bias induced by the population characteristics exposed to a given drug we will modify the comparator group by using all cases reported with drugs belonging to the corresponding ATC class 3 level.

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.

Conflicts of interest of investigators

DeclarationofInterests.pdf(88.85 KB)

Composition of steering group and observers

SteeringGroup.pdf(268.7 KB)

Signed code of conduct

Code of Conduct Declaration.pdf(687.09 KB)

Signed code of conduct checklist

Code of Conduct Checklist.pdf(938.87 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