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

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### 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

#### **Study institution contact**

François Montastruc francois.montastruc@univ-tlse3.fr

Study contact

francois.montastruc@univ-tlse3.fr

#### **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

Unknown			
Check completer	ness		
Unknown			

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No