Impact of medication adherence on mortality and cardiovascular morbidity: a population-based retrospective cohort study. IMPACT study

First published: 09/05/2017
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## Administrative details

**Study description** 

| EU PAS number     |  |
|-------------------|--|
| EUPAS19017        |  |
|                   |  |
| Study ID          |  |
| 47985             |  |
| DARWIN FILE Study |  |
| DARWIN EU® study  |  |
| No                |  |
| Study countries   |  |
| Spain             |  |
| Spain             |  |
|                   |  |

Cohort study with electronic health records in Primary Healthcare in order to assess the risk of major cardiovascular events and all-cause mortality according to the level of adherence to antiplatelet agents, betablockers, ACEI or ARB, and statins, in a population of incident cases of CHD, defined as patients with a first episode of acute coronary syndrome (ACS). This is a population-based retrospective cohort study of patients with a first episode of ACS registered in CMBD-HA of the ICS from 2006 to 2015.

#### **Study status**

Finalised

### Research institutions and networks

### **Institutions**



### Contact details

#### **Study institution contact**

## Giner-Soriano Maria mginer@idiapjgol.info

**Study contact** 

mginer@idiapjgol.info

### **Primary lead investigator**

Giner-Soriano Maria

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 30/03/2017

Actual: 30/03/2017

#### Study start date

Planned: 03/07/2017

Actual: 02/10/2017

#### Data analysis start date

Planned: 02/10/2017

Actual: 08/01/2018

#### **Date of final study report**

Planned: 31/12/2020

Actual: 31/12/2020

# Sources of funding

# More details on funding

IDIAP Jordi Gol

# Study protocol

IMPACT study Protocol 2.0\_ENCePP.pdf (149.25 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 topic:**

Disease /health condition

Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

#### If 'other', further details on the scope of the study

**ADHERENCE** 

#### **Data collection methods:**

Secondary use of data

### Main study objective:

To assess the relationship between adherences to the four pharmacological groups recommended for secondary prevention and the clinical outcomes of cardiovascular morbidity and mortality in patients with established CHD. The outcomes which are included as components of the composite endpoint are: all-cause mortality, ACS, and ischaemic stroke.

## Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code** 

(B01AC) Platelet aggregation inhibitors excl. heparin
Platelet aggregation inhibitors excl. heparin
(C07) BETA BLOCKING AGENTS
BETA BLOCKING AGENTS
(C09) AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
(C10) LIPID MODIFYING AGENTS
LIPID MODIFYING AGENTS

#### Medical condition to be studied

Acute coronary syndrome

# Population studied

#### Short description of the study population

All adult patients from SIDIAP population who have a first episode of ACS registered in CMBD-HA of the Catalan Health Institute (ICS).

#### Inclusion criteria

- Individuals ≥ 18 years with an incident diagnosis of ACS during the study period 2006-2015.
- Patients with at least two months of follow-up in SIDIAP after the index date.

#### Exclusion criteria

- Pregnant women on the index date
- Patients with a recorded diagnosis of ischaemic stroke in the six months prior to index date.
- Patients living in a nursing home on the index date.
- Patients with Alzheimer's disease or other dementias.

#### 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

Other

#### Special population of interest, other

Acute coronary syndrome patients

#### **Estimated number of subjects**

3400

# Study design details

#### **Outcomes**

To assess the relationship between adherences to the four pharmacological groups recommended for secondary prevention and the clinical outcomes of cardiovascular morbidity and mortality in patients with established CHD. The outcomes which are included as components of the composite endpoint are: all-cause mortality, ACS, and ischaemic stroke. Incidence of the composite endpoint. Relationship between baseline socio-demographic and clinical characteristics and adherence to drug therapy. Number of days on sickness leave due to any cause according to adherence to drug therapy. Prevalence of use of the four drugs. Posology prescribed.

#### Data analysis plan

Demographic and baseline characteristics of the participants will be described using frequencies and percentages for categorical variables and mean, standard deviation or median and interquartile range for continuous variables, as appropriate. Bivariate analyses will be performed using the Chi-square test for categorical variables and t-Student test or Mann-Whitney U test for continuous variables, according to their distribution. Multiple imputations by chained equations will be used to replace baseline missing values. Casecomplete and imputed data results will be compared as a sensitivity analysis. The raw and adjusted HRs for adherences will be calculated for outcome events using Cox proportional hazard regression models, and proportionality of hazards assumption will be tested.

### **Documents**

#### **Study publications**

Gerard Sotorra-Figuerola, Dan Ouchi, Rosa Morros, Maria Giner-Soriano. Impact o...

Sotorra-Figuerola G, Ouchi D, Giner-Soriano M, Morros R. Impact of adherence to...

Sotorra-Figuerola G, Ouchi D, García-Sangenís A, Giner-Soriano M, Morros R. Pha...

Sotorra Figuerola G, Ouchi D, Giner-Soriano M, Garcia-Sangenis A, Pera Pujadas

Giner-Soriano M, Sotorra Figuerola G, Cortés J, Pera Pujadas H, Garcia-Sangenis...

## 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.

### Data sources

#### Data source(s)

The Information System for Research in Primary Care (SIDIAP)

#### **Data sources (types)**

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