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

First published: 09/05/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19017

Study ID

47985

DARWIN EU® study

No

Study countries

Spain

Study description

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

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: 09/07/2026

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

Contact details

Study institution contact

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Study contact

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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

- Other

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

3.400

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. Case-complete 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