Antiplatelet Therapy during the First Year after Acute Coronary Syndrome in a Contemporary Italian Community of over 5 Million Subjects

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000154

Study ID

1000000154

DARWIN EU® study

No

Study countries

☐ Italy

Study description

An observational retrospective non-interventional cohort study that has described patterns of antiplatelet therapy (APT) during the year following a hospital diagnosis of acute coronary syndrome (ACS) and possible implications in terms of revascularization rates, rehospitalizations, and costs for the Italian National Health Service (SSN).

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 12/04/2024

Institution | Not-for-profit | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Letizia Dondi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/01/2021

Study start date
Actual: 08/02/2021

Date of final study report
Actual: 08/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This research was partially funded by Sanofi Italy. No grant number has been generated. The funders had no role in the design of the study; in the collection, analyses, or interpretation of the data; in the writing of the manuscript, or in the decision to publish the results.

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

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Patients discharged (index date) with ACS diagnosis in 2017 were identified by an algorithm. Patients were characterized by revascularization rates at index date, APT at one month and one year and rehospitalizations and healthcare costs during follow-up.

Main study objective:
To investigate apparent discrepancies between guideline-recommended and real-world APT and the implications of such divergences for patients and healthcare systems.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Antiplatelets

Study drug International non-proprietary name (INN) or common name
ACETYLSALICYLIC ACID
CLOPIDOGREL
PRASUGREL
TICAGRELOR

Anatomical Therapeutic Chemical (ATC) code
(B01AC04) clopidogrel

clopidogrel

(B01AC05) ticlopidine

ticlopidine

(B01AC06) acetylsalicylic acid

acetylsalicylic acid

(B01AC07) dipyridamole

dipyridamole

(B01AC22) prasugrel

prasugrel

(B01AC24) ticagrelor

ticagrelor

(B01AC30) combinations

combinations

Medical condition to be studied

Acute coronary syndrome

Population studied

Age groups

All

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

Inpatient and outpatient

Summary results

From the 2017 ReS database, 7966 (1.46x1000 inhabitants) were discharged alive with an ACS diagnosis. Most were >69 years and male. Of these, 83% (6640/7966) received at least 1 recommended antiplatelet agent within one month (treated group): 23% (1870/7966) as single and 60% (4770/7966) as dual APT. Among the 53% undergoing revascularization, 81% received dual APT at one month. Of the 78% with the same APT at one year, 66% showed appropriate coverage. For subjects treated and untreated with APT at one month, one-year rehospitalization rates were 54% and 66%, respectively, and mean per capita costs were EUR 14,316 and EUR 16,552, respectively (hospitalization driving >80% of costs).

Documents

Study publications

Antiplatelet Therapy during the First Year after Acute Coronary Syndrome in a C...

Data management

Data sources

Data source(s), other

Fondazione ReS database

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes