Dual antiplatelet therapy for prolonged secondary prevention of acute coronary events (DEEPSPACE)

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Study Ongoing

Administrative details

EU PAS number

EUPAS29177

Study ID

44220

DARWIN EU® study

No

Study countries

☐ France

Study description

Dual antiplatelet therapy (DAPT) is recommended for one year after an acute coronary syndrome (ACS), but the benefits and risks of longer duration of DAPT remain disputed. The PEGASUS-TIMI 54 clinical trial found a beneficial effect of prolonged DAPT with ticagrelor in chronic stable high-risk patients, but its generalizability is uncertain. The latest recommendations from the European Society of Cardiology remain relatively conservative considering that extension of DAPT beyond 1 year (up to 3 years) in the form of aspirin plus ticagrelor 60 mg bid may be considered in patients who have tolerated DAPT without a bleeding complication and having an additional risk factor for ischaemic events. In this context, the DEEPSPACE study purpose is to compare in real-life event rate (i.e. composite criterion of ACS, stroke, major bleeding, or death for main outcome, and individual events for secondary outcomes) on DAPT with any of the three P2Y12 antagonists (clopidogrel, ticagrelor, or prasugrel) plus aspirin to aspirin alone, over 3 years beyond one year after ACS, using the French nationwide claims database (SNDS). The cohort will include all patients hospitalised for an initial ACS (trigger event) between 2013 and 2014, and having one year of event-free DAPT after this initial ACS. The index date will be the one-year anniversary date for the ACS discharge, and each patient will be followed 3 years or until death and will have 2-year history prior the index date in the database. It is expected 50 000 patients included in the study after one-year event-free on DAPT with an event occurrence estimate to 5 200 composite events and 1 000 deaths. The outcomes will be described during the exposure period according to treatment groups in terms of crude incidence rate (Normal approximation), cumulative incidence rate (Kaplan-Meier estimator or Cumulative Incidence Function), and risk factors of outcomes (Cox proportional hazards models or Fine and Grey models).

Study status

Ongoing

Research institutions and networks

Institutions

University of Bordeaux

France

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Institution | Educational Institution

Contact details

Study institution contact

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Primary lead investigator

Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/06/2019

Study start date

Planned: 31/12/2019

Actual: 26/02/2020

Data analysis start date
Planned: 03/05/2021

Date of final study report
Planned: 31/03/2023

Sources of funding

- Other

More details on funding

French Ministry of Health (PHRCN-18-0745)

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

Disease epidemiology

Drug utilisation

Main study objective:

The main objective is to compare event rates on DAPT with any of the three P2Y12 antagonists plus aspirin to single antiplatelet therapy (SAPT) with aspirin alone, over 3 years beyond one year after initial coronary event.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC04) clopidogrel

clopidogrel

(B01AC06) acetylsalicylic acid

acetylsalicylic acid

(B01AC22) prasugrel

prasugrel

(B01AC24) ticagrelor

ticagrelor

Medical condition to be studied

Acute coronary syndrome

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

50000

Study design details

Outcomes

Composite of all-cause death, ACS, stroke, or major bleeding. All-cause death, ACS (STEMI, NSTEMI and unstable angina), stroke (ischemic or undefined stroke), major bleeding (intracranial bleeding, upper GI bleeding, other major bleeding).

Data analysis plan

The following analyses will be performed: - Description of patients at baseline and during the 3 years of follow-up, overall and by treatment group with standardized differences before and after adjustment for / matching on hdPS, - A hdPS will be estimated for each comparison (clopidogrel, ticagrelor or

prasugrel + aspirin vs aspirin alone) using a multivariable logistic regression model with multiple data dimensions from patients and healthcare reimbursements before index date, - Estimation of outcome incidences during the drug exposure period (all and matched patients) in each treatment group using Kaplan-Meier estimator for death and composite criterion, or cumulative incidence function estimate for other single outcomes in order to take into account death as competing risk, - Comparison of outcome rates between treatment groups using Cox proportional hazard models for death and composite criterion, and Fine and Gray competing risks models for non-fatal outcomes.

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 sources (types)

Administrative healthcare records (e.g., claims)

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