Observational study of post-myocardial infarction with a long follow-up (EOLE)

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/49880

EU PAS number

EUPAS10726

Study ID

49880

DARWIN EU® study

No

Study countries

France

Study description

The EOLE study was requested by French authorities at the time of new omega-3 supplementation marketing for secondary prevention of post-myocardial infarction. The main research question is to assess the impact of recommended cardiovascular drugs (beta-blockers, acetylsalicylic acid or other antiplatelet agents, statins or other lipid lowering agent, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, and omega-3 supplementation), and dietary lifestyle guidelines in real-life to all cause mortality in secondary prevention of myocardial infarction in France after 6 years of follow-up. Hospital and non-hospital cardiologists included 5527 patients from April 2006 to June 2009. Socio-demographic data, myocardial infarction characteristics, cardiovascular risk factors, history and associated cardiovascular diseases, last lab test results, cardiovascular drugs, cardiovascular rehabilitation program, tobacco use, drugs taken, hospitalisations since myocardial infarction and vital status were collected using a medical questionnaire completed at first postmyocardial infarction consultation, and a patient self-administered questionnaire filled out at inclusion, 6 month, 2, 3, 4, 5 and 6 years. At 6 years follow-up, the vital status of all patients will be ascertained from the national death registry using a standard approved national procedure whereby the national identification database is searched (decree #98-37 of 16 January 1998, modified procedure INSEE/INSERM), and failing that, through patient/relatives/physicians. An interim analysis will be planned after 3.5 years of follow-up

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

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Institution Educational Institution	Hospital/Clinic/Other health care facility
Not-for-profit ENCePP partner	

Contact details

Study institution contact

Patrick Blin

Study contact

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Primary lead investigator Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed Actual: 21/12/2005

Study start date

Actual: 01/03/2006

Data analysis start date Actual: 05/01/2009

Date of interim report, if expected Actual: 03/02/2013

Date of final study report Planned: 30/06/2016 Actual: 12/07/2016

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Pierre Fabre Médicament

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness Disease epidemiology Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To assess the impact of recommended secondary prevention drugs and dietary lifestyle guidelines in real-life practice to all cause mortality in secondary prevention of myocardial infarction in France after 6 years of follow-up.

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 (C07A) BETA BLOCKING AGENTS BETA BLOCKING AGENTS (C09A) ACE INHIBITORS, PLAIN ACE INHIBITORS, PLAIN (C09C) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN (C10AA) HMG CoA reductase inhibitors HMG CoA reductase inhibitors (C10AB) Fibrates Fibrates (C10AC) Bile acid sequestrants Bile acid sequestrants (C10AD) Nicotinic acid and derivatives Nicotinic acid and derivatives

Medical condition to be studied

Myocardial infarction

Population studied

Short description of the study population

Subjects with post-myocardial infarction treated with cardiovascular drugs including beta-blockers, acetylsalicylic acid or other antiplatelet agents, statins or other lipid lowering agent, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, and omega-3 supplementation identified from April 2006 to June 2009.

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

Myocardial infarction patients

Estimated number of subjects

5527

Study design details

Outcomes

All cause mortality at 6 years follow-up, Coronary & cardiovascular mortalityCoronary & cardiovascular morbi-mortalityPersistence of prescription of recommended secondary prevention drugs (according to the European & the French recommendations)Differential between cardiologist prescription & patient declaration for recommended secondary prevention drugsDietary lifestyle guidelines follow-upEvolution of self-perceived health

Data analysis plan

Statistical analysis will be carried out by the Bordeaux pharmacoepi according to a documented and approved Statistical Analysis Plan (SAP). Statistical analysis will be performed after database lock using SAS® software (SAS Institute, last version, North Carolina, USA). Blind double programming will be used for the main outcome measures. Qualitative variables (dichotomous or categorical) will be described in terms of number and frequency. Quantitative variables will be described in terms of mean, standard deviation, median, first and third quartiles, as well as deciles. The Kaplan Meier estimate will be used to estimate the occurrence of all-cause death. The Cox proportional hazard regression model adjusted for gender, age, cardiovascular risk factors, other myocardial infarction prevention drugs and propensity score to be exposed at inclusion will be used to estimate the risk of death in patients exposed and not exposed to each secondary prevention drug.

Documents

Study publications

Droz-Perroteau C, Blin P, Dureau-Pournin C, Thomas D, Danchin N, Tricoire J, Pa...

Data management

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No