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

**First published:** 20/08/2015

**Last updated:** 23/07/2024

Study Finalised

## Administrative details

**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 post-myocardial 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

**First published:** 07/02/2023

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

# Contact details


**Study institution contact**

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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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

**Data collection methods:**

Primary data collection

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**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

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**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.

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**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)

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**Special population of interest**

Other

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**Special population of interest, other**

Myocardial infarction patients

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**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

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**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

## 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)**

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