EOLE - Observational study of Long-term follow-up of post-myocardial infarction

Head :Moore Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Blin Patrick, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Last update : 10/26/2017 | Version : 2 | ID : 2818

General

Identification

Detailed name	Observational study of Long-term follow-up of post-myocardial infarction
Sign or acronym	EOLE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS 05.484, CNIL 906042

General Aspects

Medical area	Cardiology
Health determinants	Lifestyle and behavior Medicine Nutrition Occupation
Keywords	Acute Myocardial Infarction (AMI), lifestyle and dietary recommendations, cardiovascular treatments, secondary prevention, mortality, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

Name of the director	Moore
Surname	Nicholas
Address	Bât du Tondu - Case 41- 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33 (0)5 57 57 46 75
Email	nicholas.moore@u-bordeaux2.fr

Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux
Name of the director	Blin
Surname	Patrick
Address	Bât du Tondu - Case 41- 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33 (0)5 57 57 46 75
Email	patrick.blin@pharmaco.u-bordeaux2.fr
Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux

Collaborations

Participation in projects, networks and consortia	No

Funding

Funding status	Private
Details	Pierre Fabre Médicament (unconditional support)

Governance of the database

Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public
Presence of scientific or steering committees	Yes

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study

Database recruitment is carried out by an intermediary	A selection of health care professionals
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Patients are included by cardiologists who are themselves selected from a random sample of hospital and non-hospital cardiologists in metropolitan France.

Database objective

Main objective	The main objective is to assess in real situations of use the impact of cardiovascular medications and recommended lifestyle and dietary recommendations on all-cause mortality in secondary prevention of myocardial infarction.
Inclusion criteria	Patient with recent (?3 months) acute myocardial infarction (first or recurrent heart attack); Patient seen during the first or second consultation after acute myocardial infarction; Infarct defined by the presence at least of two among the following criteria: symptomatic (characteristic pain), electric (Q wave and / or ST elevation in at least two adjacent leads), enzymatic (elevated CPKMB and / or troponin greater than 2 twice the normal value); Patient who may be followed for 6 years; Patient without a non-cardiovascular disease that is life-threatening in the short term (?3 months); Patient not included in a clinical trial of an non marketed drug; Patient not affected by a language barrier (unable to read the information sheet or complete the self-administered questionnaires); Patient agreeing to participate.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	National

Detail of the geography area	Hospital and non-hospital cardiologists in metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2015

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	5538

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Administrative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire Internet self-questionnaire Phone interview
Details of collected declarative data	Questionnaire diet, physical activity before and after myocardial infarction, tobacco use, drugs taken, and hospitalisations after myocardial infarction of inclusion
Administrative data (detail)	Patient name , first name, date and place of birth, phone number and address, contact details of the general practitioner.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medicines consumption

Procedures	
Data collection method	Inclusion data are collected by cardiologists and patients via a paper questionnaire. Follo-up data are collected by cardiologists (only at 6 and 24 months of follow up in the first includion period) and by patients via an eCRF or a paper questionnaire.
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.)
Details on monitoring of participants	The total follow-up is 6 years with an evaluation at 6 months, 24 months, 3 years 4 years 5 years 6 years via a self-administered questionnaire. Patients may fill-out these questionnaires via the internet (eCRF) or by postal mail using a paper questionnaire. The data collected in this questionnaire concern dietary habits since the AMI (only at 6 and 24 months of follow-up for patients included during the first inclusion period), treatments taken, physical activity, smoking, current health status, and hospitalizations. Follow-up by cardiologists concerns only patients included in the first inclusion period with an evaluation at 6 and 24 months (vital status, cardiovascular events, clinical and laboratory data, prescribed cardiovascular treatments). Vital status determination of included patients at 3.5 years and 6 years will be performed using the INSERM / INSEE procedure.
Links to administrative sources	Yes
Linked administrative sources (detail)	RNIPP, CéPIDC
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/EOLE/
Description	List of publications in HAL
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Confidential study reports are submitted to the Pharmaceutical company and health authorities. The study reports and scientific communications (posters, articles, ...) are validated by the study

	Scientific Committee. Ownership of study data is the subject of an agreement between the University Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only