

CALIPSO - Prognostic value of peripheral arterial disease on 1-year ischemic outcomes in outpatients with a recent history of ACS

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General

Identification

Detailed name	Prognostic value of peripheral arterial disease on 1-year ischemic outcomes in outpatients with a recent history of ACS
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Sign or acronym	CALIPSO
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N° 08.098
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General Aspects

Medical area	Cardiology
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Others (details)	Peripheral Arterial Obstructive Disease (PAOD) in patients who have had an Acute coronary syndrome
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Keywords	PAD, ABI, prognostic value, ischemic events, Cardiology, ACS, secondary prevention
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Scientific investigator(s) (Contact)

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Unit	Bristol-Myers Squibb
Collaborations	
Funding	
Funding status	Private
Details	Bristol-Myers Squibb France / Sanofi Aventis France
Governance of the database	
Sponsor(s) or organisation(s) responsible	Bristol-Myers Squibb France (BMS)
Organisation status	Private
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 institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Random sampling in clusters.
Database objective	
Main objective	Determine the prognostic value of PAD (symptomatic or asymptomatic) on 1-year ischemic outcomes (death, myocardial ischemic recurrence, stroke, revascularization, rehospitalization for ischemic events) in patients with a recent ACS.

Inclusion criteria	<p>Register part : M/F patient, ≥ 18 years, outpatient seen by private cardiologists, with a recent history of ACS with or without ST-segment elevation in the last 12 months.</p> <p>Study Part : patients from the register (2 first consecutive pts in the register without PAD) + (2 first consecutive patients in the register with symptomatic PAD or asymptomatic PAD and ABI < 0.9)</p>
Population type	
Age	<p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>
Population covered	Sick population
Gender	<p>Male</p> <p>Woman</p>
Geography area	National
Detail of the geography area	Metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	Registre/register : 2883 Cohorte/cohort :1760
Data	
Database activity	Data collection completed
Type of data collected	<p>Clinical data</p> <p>Biological data</p>

Clinical data (detail)	Direct physical measures
Biological data (detail)	fasting glucose, creatinine, glycosylated hemoglobin, total cholesterol, HDL, LDL, triglycerides
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Paper CRF
Participant monitoring	Yes
Details on monitoring of participants	Month 0 and month 9
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only