OPTIMEV - Optimising History Taking for Evaluating The Risk of Venous Thromboembolism

Head :Bosson Jean-Luc, CIC GrenobleEquipe Themas laboratoire TIMC Imag UMR CNRS 5525
Sevestre Marie Antoinette

Last update : 08/11/2014 | Version : 2 | ID : 5361

General

Identification

Detailed name	Optimising History Taking for Evaluating The Risk of Venous Thromboembolism
Sign or acronym	OPTIMEV
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	N° CCTIRS : 04-459 N° CNIL : 905040 ?05-1118 N° CLINICALTRIALS : NCT00670540

General Aspects

Medical area	Cardiology Hematology Pneumology
Keywords	lower limb deep vein thrombosis, superficial venous thrombosis, post-thrombotic syndrome, pulmonary embolism, Venous thromboembolism, chronic disease, quality of life

Scientific investigator(s) (Contact)

Name of the director	Bosson
Surname	Jean-Luc
Address	Pole Santé Publique pavillon taillefer Chu Grenoble 38700 La Tronche
Phone	+ 33 (0)4 76 76 50 47
Email	jlbosson@imag.fr
Unit	CIC GrenobleEquipe Themas laboratoire TIMC Imag UMR CNRS 5525
Organization	INSERM - Institut National de la Santé et de la

	Recherche
Name of the director	Sevestre
Surname	Marie Antoinette
Address	Service de Médecine Vasculaire CHU Amiens
Email	sevestre.marie-antoinette@chu-amiens.fr
Organization	CHU
Collaborations	
Funding	
Funding status	Mixed
Details	Le programme hospitalier de recherche clinique PHRCSanofi AventisCIC Grenoble et service de Médecine Vasculaire Grenoble
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Société Française de Médecine Vasculaire
Organisation status	Public
Sponsor(s) or organisation(s) responsible	CHU Grenoble
Organisation status	Public
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 A selection of health institutions and services

Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Patients referred to a vascular medicine physician for clinically suspected thromboembolism. All patients are enrolled after been seen in one day over 4 recruitment periods (4 seasons)

Database objective

Main objective	To evaluate current risk factors that fit today's practice and long-term prognosis for different anatomical and clinical forms of symptomatic thromboembolism (proximal and distal deep vein thrombosis, superficial venous thrombosis, pulmonary embolism) Follow-up covers recurrent VTE, arterial thrombotic events (coronary, CVA, PAD), onset of cancer, haemorrhagic stroke, post-thrombotic syndrome and death.
Inclusion criteria	Adult patients with clinical signs of symptomatic thromboembolism classified after inclusion for VTE+ patients (thromboembolism confirmed through further objective examination) or VTE- patients (thromboembolism ruled out by further examination)

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	France, 350 investigating vascular medicine physicians from CHU, CHG, clinics and private practices

Data collection

Dates

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

Date of last collection (YYYY or MM/YYYY)	2014
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	8256
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Phone interview
Paraclinical data (detail)	Doppler ultrasonography and Pulmonary CT examination report, hospital report
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
Procedures	
Data collection method	Patient characteristics entered at baseline on an e-CRF where quality is monitored electronically Follow-up entered after all target events were validated by a critical events committee (2 physicians evaluating examination and hospital reports) by CRA on an e-CRF
Participant monitoring	Yes
Details on monitoring of participants	Clinical research associates specialising in vascular disease conducted follow-up telephone interviews with PTS evaluation (Villalta score), quality of life evaluation as well as events involving venous and arterial thrombosis, cancer, haemorrhagic stroke and death.

Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://recherche-clinique.ujf-grenoble.fr/OPTIMEV/
Link to the document	http://tinyurl.com/OPTIMEV
Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=optimev+AND+%28Bosson+JL[Author]+OR+Sevestre+MA[Author]%29+OR+22429908[uid]
Description	List of publications in Pubmed

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