

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

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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)

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Organization INSERM - Institut National de la Santé et de la

Recherche

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Organization	CHU

Collaborations

Funding

Funding status	Mixed
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Details	Le programme hospitalier de recherche clinique PHRCSanofi AventisCIC Grenoble et service de Médecine Vasculaire Grenoble
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Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
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Organisation status	Public
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Sponsor(s) or organisation(s) responsible	Société Française de Médecine Vasculaire
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Organisation status	Public
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Sponsor(s) or organisation(s) responsible	CHU Grenoble
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Organisation status	Public
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
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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.
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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)
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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)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	France, 350 investigating vascular medicine physicians from CHU, CHG, clinics and private practices
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2006
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Date of last collection (YYYY or MM/YYYY)	2014
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Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
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Details of the number of individuals	8256
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Declarative data Paraclinical data
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Clinical data (detail)	Direct physical measures Medical registration
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Declarative data (detail)	Paper self-questionnaire Phone interview
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Paraclinical data (detail)	Doppler ultrasonography and Pulmonary CT examination report, hospital report
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
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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
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Participant monitoring	Yes
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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.
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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\[uid\]](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