FOTO - French observational survey about 3 months incidence of symptomatic venous thromboembolic events on patients with total hip or knee prosthesis

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Organization

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| General | | |
| Identification | | |
| Detailed name | French observational survey about 3 months incidence of symptomatic venous thromboembolic events on patients with total hip or knee prosthesis | |
| Sign or acronym | FOTO | |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL | |
| General Aspects | | |
| Medical area | Hematology | |
| Keywords | Symptomatic thromboembolic events, total hip or knee prostheses | |
| Scientific investigator(s) (Contact) | | |
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Collaborations

Funding

Funding status Private

Sanofi-Synthelabo **Details**

Governance of the database

Sponsor(s) or organisation(s)

Assistance Publique - Hôpitaux de Paris Hôpital responsible **Bichat**

| Organisation status | Public |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sponsor(s) or organisation(s) responsible | Sanofi-Synthelabo |
| Organisation status | Private |
| Additional contact | |
| Main features | |
| Type of database | |
| Type of database | Study databases |
| Study databases (details) | Longitudinal study (except cohorts) |
| 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. | Representative sample of patients operated for a total hip or knee prostheses. Each investigator selects consecutively his patients scheduled for a total hip or knee prostheses |
| Database objective | |
| Main objective | Evaluating at 3 months the incidence of Symptomatic thromboembolic events |
| Inclusion criteria | Male or female, 18 years old or more, with total hip or knee prostheses |
| Population type | |
| Age | Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) |
| Population covered | Sick population |
| Gender | Male Woman |
| Geography area | National |
| Detail of the geography area | France (130 orthopaedic centers) |

| Data collection | |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dates | |
| Date of first collection (YYYY or MM/YYYY) | 2003 |
| Size of the database | |
| Size of the database (number of individuals) | [1000-10 000[individuals |
| Details of the number of individuals | 1770 |
| Data | |
| Database activity | Data collection completed |
| Type of data collected | Declarative data |
| Declarative data (detail) | Face to face interview |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity Health event/mortality Health care consumption and services |
| Care consumption (detail) | Hospitalization |
| Procedures | |
| Data collection method | At each patient corresponds a unique data collection form. Information is collected during the pre-operative examination, leaving the hospital and at 3 months. At 3 months, the patient will send back to his doctor the data collection form received before leaving the hospital, to get informed about his good health. |
| Participant monitoring | Yes |
| Details on monitoring of participants | Follow-up for 3 months |
| Links to administrative sources | No |
| Promotion and access | |
| Promotion | |

| Link to the document | http://tinyurl.com/Hal-FOTO |
|----------------------|-------------------------------------------------------------------------------------------------------|
| Description | List of publications in HAL |
| Link to the document | http://www.ncbi.nlm.nih.gov/pubmed/? term=%28Samama+OR+Barre+OR+Ravaud+OR+ Mismetti%29+AND+foto |
| Description | List of publications in Pubmed |

| Access | |
|---------------------------------------------------------------------------------------------|---------------------------------|
| Terms of data access (charter for data provision, format of data, availability delay) | To be defined |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |