

ESTHER - EStrogen THromboEmbolism Risk

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General

Identification

Detailed name EStrogen THromboEmbolism Risk

Sign or acronym ESTHER

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL 999271, CCPPRB Brest 24 aout 1998, DGS 980433

General Aspects

Medical area Cardiology
Endocrinology and metabolism

Health determinants Iatrogenic

Others (details) Menopause hormone therapy

Keywords Menopause, hormone therapy, progesterone, oestrogen, progestin

Scientific investigator(s) (Contact)

Name of the director Scarabin

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Organization Institut National de la Santé et de la Recherche

Collaborations

Participation in projects, networks and consortia Yes

Funding

Funding status Mixed

Details - Fondation de France - Fondation pour la Recherche Médicale - Institut Nationale de la Santé et de la Recherche Médicale - Besins International - Sanofi

Governance of the database

Sponsor(s) or organisation(s) responsible Institut National de la Santé et de la Recherche Médicale

Organisation status Public

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Case control study

Database recruitment is carried out by an intermediary A selection of health institutions and services
A population file

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. Hospital and community case subjects, hospital and community case-controls (randomly selected from electoral registers)

Database objective

Main objective To evaluate the risk of venous thromboembolism in connection with hormone therapy for menopause while considering the administration route for oestrogen and types of progestin.

Inclusion criteria - Women - between 45 and 65 years of age - menopausal - with no cardiovascular history or breast cancer

Population type

Age	Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Woman
Geography area	National
Detail of the geography area	France (multicentric hospital and general population study)
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	1999
Date of last collection (YYYY or MM/YYYY)	2003
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	728 - 195 sujets atteints/cases - 533 témoins/controls
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Face to face interview
Presence of a biobank	Yes
Contents of biobank	DNA
Details of biobank content	DNA bank
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	Selection and questionnaire by dedicated CRA in

each centre

Classifications used ----

Participant monitoring No

Links to administrative sources No

Promotion and access

Promotion

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/12927428>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/15978114>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/16301339>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/16409454>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/16706969>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/17309934>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/18217166>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/18495631>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/18628519>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/19320825>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/19782484>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/21107315>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/12927428>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/16409454>

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Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/18495631>

Access

Terms of data access (charter for data provision, format of data, availability delay)

Contact the scientist in charge

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only