PRESSTO - PRogestogens, EStrogens and STrOke

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General		
Ide	entification	
De	tailed name	PRogestogens, EStrogens and STrOke
Sig	n or acronym	PRESSTO
nu agi He	IIL registration number, mber and date of CPP reement, AFSSAPS (French alth Products Safety Agency) thorisation	CCTIRS n°11.208 et CNIL n°DR-2011-473
Ge	neral Aspects	
Me	edical area	Cardiology

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Medical area	Cardiology Neurology
Others (details)	Stroke (cerebrovascular accident)
Keywords	Hormone therapy for menopause, oestrogen, progestin

Scientific investigator(s) (Contact)		
(Contact)		

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Unit	Équipe Hormones et Maladies Cardiovasculaires UMR-S 1018			
Organization	Institut National de la Santé et de la Recherche			
Collaborations				
Funding				
Funding status	Public			
Details	IReSP			
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			
Database recruitment is carried out as part of an interventional study	No			
Additional information regarding sample selection.	Hospital cases are identified by PMSI data (codes corresponding to primary or associated diagnosis). Women considered to be in good health are randomly selected from the original cohort as controls and matched with cases according to age and place of residence (4 controls per case).			
Database objective				
Main objective	To evaluate the risk of cardiovascular disease (cerebrovascular accident, myocardial infarction			

and pulmonary embolism) in connection with
hormone therapy for menopause while considering
the administration route for oestrogen and types of
progestin.

Inclusion criteria	- Women - between 50 and 70 years old -
	menopausal

	menopausal
Population type	
Age	Adulthood (45 to 64 years)
Population covered	General population
Gender	Woman
Geography area	National
Detail of the geography area	France
Data collection	

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Dates

Date of first collection (YYYY or MM/YYYY)

2009

Size of the database

Size of the database (number	of
individuals)	

Greater than 20 000 individuals

Details of the number of individuals

100000 - 20000 cas / case - 80000 témoins / controls

Data

Database activity	Data collection completed

Type of data collected Clinical data Administrative data

Direct physical measures Clinical data (detail)

Medical registration

Administrative data (detail) INSEE commune code

Presence of a biobank No

Health parameters studied Health event/morbidity Health event/mortality

Health care consumption and services

Care consumption (detail)

Medical/paramedical consultation Medicines consumption

Procedures	
Participant monitoring	No
Links to administrative sources	Yes
Linked administrative sources (detail)	Basic health insurance (SNIIR-AM)
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Anonymised data is transmitted as an encrypted file whose decryption key is generated by the coordinator. Only those involved in the project have access to data and are under the responsibility of the coordinator.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only