ASSESS - Assessment of Systemic Involvement and Progression for Patients with Primary Sjogren's Syndrome

Head :Gottenberg Jacques-Eric, U1109 Immuno-rhumatologie moléculaire

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General

Identification

Detailed name	Assessment of Systemic Involvement and Progression for Patients with Primary Sjogren's Syndrome
Sign or acronym	ASSESS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP 26/01/2007 N° 0711468

General Aspects

Medical area	Immunology
Keywords	Prevalence, risk factor

Scientific investigator(s) (Contact)

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Organization	CHU

Collaborations

Funding

Funding status	Public

Details	Ministère de la santé (Programme Hospitalier de Recherche Clinique 2005 P060228)

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU Strasbourg
Organisation status	Public

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

Database objective

Main objective	To prospectively determine for the first time the prevalence and risk factors for systemic complications and lymphoma in primary Sjögren's syndrome.
Inclusion criteria	- Men or women - adults - patients in tertiary centres for autoimmune diseases

Population type

Age	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 (15 Centres)

Data collection

Dates	
Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	395
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures
Presence of a biobank	Yes
Contents of biobank	Serum DNA DNAc/RNAm
Details of biobank content	----------
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Paper case report form (CRF) completed by the investigator or co-investigator. CRFs are then sent to a data manager for input.
Participant monitoring	Yes
Details on monitoring of participants	Follow-up for serious adverse events.
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Hal-ASSESS
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-ASSESS
Description	List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data unavailable to other researchers, except for authorisation requests for IP data mining to the coordinating investigator
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only