

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

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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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Unit	U1109 Immuno-rhumatologie moléculaire
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
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Description	List of publications in HAL
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Link to the document	http://tinyurl.com/Pubmed-ASSESS
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Description	List of publications in Pubmed
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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
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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