

KaRen - Karolinska-Rennes Cohort: Cardiac Dyssynchrony in Patients with Heart Failure and Preserved Ejection Fraction

Head : Daubert Jean-Claude, Centre Cardio-Pneumologique, Hôpital Pontchaillou, CHU de Rennes
Donal Erwan, Service de Cardiologie et CIC-IT 804 ? LTSIINSERM U 642 Hôpital Pontchaillou

Last update : 05/12/2015 | Version : 2 | ID : 8678

General

Identification

Detailed name	Karolinska-Rennes Cohort: Cardiac Dyssynchrony in Patients with Heart Failure and Preserved Ejection Fraction
Sign or acronym	KaRen
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL no. 908071 on 23/03/2009

General Aspects

Medical area	Cardiology
Keywords	atrial arrhythmia, left ventricular ejection fraction, HF, heart failure, LVEF, prognosis, prevalence

Scientific investigator(s) (Contact)

Name of the director	Daubert
Surname	Jean-Claude
Address	CHU de Rennes, Centre de Cardio-Pneumologie, 35033 Rennes, France
Email	jean-claude.daubert@chu-rennes.fr
Unit	Centre Cardio-Pneumologique, Hôpital Pontchaillou, CHU de Rennes
Organization	CHU
Name of the director	Donal
Surname	Erwan

Address	Hôpital Pontchaillou, CHU de Rennes, 35033 Rennes France
Email	erwan.donal@chu-rennes.fr
Unit	Service de Cardiologie et CIC-IT 804 ? LTSIINSERM U 642Hôpital Pontchaillou
Organization	CHU de

Collaborations

Funding

Funding status Private

Details French Cardiology Society

Governance of the database

Sponsor(s) or organisation(s) responsible Société Française de Cardiologie

Organisation status Private

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Cohort 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

Database objective

Main objective The main aim is to test the prognostic value of electrical or mechanical cardiac dyssynchrony and to determine prevalence and characteristics in patients with heart failure and preserved left ventricular ejection fraction.

Inclusion criteria - Hospital visit OR hospitalisation for heart failure symptom;

- Clinical signs of HF;
- HF according to the Framingham criteria: 2 major criteria or 1 major + 2 minor criteria;
- LVEF (Left Ventricular Fraction) greater or equal to 45% by echocardiography;
- NT-proBNP greater than 300 pg/mL or BNP greater than 100.

Exclusion criteria:

- Evidence of primary hypertrophic or restrictive cardiomyopathy, or systemic illness known to be associated with infiltrative heart disease;
- Known right heart failure by pulmonary or pulmonary vascular disease not related to the left heart;
- Pericardial constriction;
- Restrictive or obstructive pulmonary disease, as evidenced by the requirement for home oxygen;
- End-stage renal disease currently requiring dialysis;
- Bi-ventricular pacemaker (CRT-P + ICD);
- Acute coronary syndrome.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
-----	---

Population covered	Sick population
--------------------	-----------------

Gender	Male Woman
--------	---------------

Geography area	International
----------------	---------------

Detail of the geography area	Sweden and France (Bordeaux, Créteil, Lille, Lyon, Marseilles, Montpellier, Nantes, Rennes, Paris, Rouen, Nancy).
------------------------------	---

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	10/2008
--	---------

Date of last collection (YYYY or MM/YYYY)	2012
---	------

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	362 (May 2012)
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Treatment, medical history.
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Quality of life questionnaire.
Paraclinical data (detail)	Electrocardiogram.
Biological data (detail)	Standard biology + NT-proBNP or BNP.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	Follow-up at 4-8 weeks (treatment, events since enrolment, vital status, medical examination and quality of life questionnaire), 6 months, 12 months and 18 months.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/HAL-KAREN
Description	List of publications in HAL

Link to the document	http://tinyurl.com/Pubmed-Karen
----------------------	---

Description	List of publications in Pubmed
-------------	--------------------------------

Access

Terms of data access (charter for data provision, format of data, availability delay)	Results via publications. Contact the scientist in charge for further information.
---	--

Access to aggregated data	Access on specific project only
---------------------------	---------------------------------

Access to individual data	Access on specific project only
---------------------------	---------------------------------