

# COFRASA / GENERAC - Factors Favouring Aortic Stenosis

Head :Messika-Zeitoun David, SERVICE DE CARDIOLOGIE DU PROFESSEUR VAHANIAN

Last update : 08/07/2014 | Version : 1 | ID : 60116

General	
Identification	
Detailed name	Factors Favouring Aortic Stenosis
Sign or acronym	COFRASA / GENERAC
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL : 31/07/2006
General Aspects	
Medical area	Cardiology
Others (details)	Aortic stenosis
Keywords	heart failure, aortic valve replacement, aortic valve, vascular atherosclerotic disease, Death, myocardial infarction, stroke, intima-media.
Scientific investigator(s) (Contact)	
Name of the director	Messika-Zeitoun
Surname	David
Address	75018 PARIS
Email	david.messika-zeitoun@bch.aphp.fr
Unit	SERVICE DE CARDIOLOGIE DU PROFESSEUR VAHANIAN
Collaborations	
Funding	
Funding status	Public
Details	AP-HP, DRC

Governance of the database	
Sponsor(s) or organisation(s) responsible	AP-HP
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 as part of an interventional study	No
Additional information regarding sample selection.	Prospective Other bodies active in creating this cohort: CHU, CHG, independent physicians, multiple recruitment sources but centralised evaluation at Bichat Inclusion cut-off date: 01/01/2011
Database objective	
Main objective	To determine factors favouring aortic stenosis progression and more specifically the effect of biological markers for inflammation, coagulation, platelet aggregation and matrix metalloproteinases. Secondary objectives: - To assess the relationship between the increase in AS and progression of vascular atherosclerosis; - To research genetic susceptibility factors associated with AS with candidate genes (fetuin-A, matrix-GLA protein, vitamin D receptor) and genomewide association studies; - To identify the relationships between genetic polymorphisms of fetuin-A, matrix-GLA protein, vitamin D receptor with 1) plasma levels for fetuin-A, MGP, vitamin D and parathyroid hormone, 2) haemodynamic severity stenosis and 3) the progression of AS.
Inclusion criteria	Patient group (aortic stenosis) - age $\geq 18$ years - pure (no or minimal aortic valve stenosis), isolated (no valve disease $\geq$ grade 2/4), "degenerative" aortic valve stenosis; - no known severe renal insufficiency (creatinine clearance $< 30$ ml/min); - Patients affiliated with a social security scheme. Control group: age $\geq 18$ years, no known first degree relative with aortic valve stenosis: no valve

disease  $\geq$  grade 2/4; - no known severe renal insufficiency (creatinine clearance  $< 30$  ml/min); - - Patients affiliated with a social security scheme.

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	Regional
French regions covered by the database	Île-de-France
Detail of the geography area	Île-de-France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	11/2006
Date of last collection (YYYY or MM/YYYY)	01/2011
Size of the database	
Size of the database (number of individuals)	[1000-10 000[ individuals
Details of the number of individuals	- 1000 patients présentant un rétrécissement aortique / cases - 1500 contrôles / controls
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures

Medical registration

Declarative data (detail)

Face to face interview

Paraclinical data (detail)

Imaging: echocardiography, carotid ultrasound, ECG.

Biological data (detail)

Blood (+ aortic valve specimen for operated patients)

Presence of a biobank

Yes

Contents of biobank

Whole blood  
Serum  
Plasma  
DNA

Details of biobank content

Serum bank, plasma bank, DNA bank, tissue bank (aortic valve specimen for operated patients)

Health parameters studied

Health event/morbidity  
Health event/mortality  
Health care consumption and services  
Quality of life/health perception

Care consumption (detail)

Hospitalization  
Medical/paramedical consultation  
Medicines consumption

## Procedures

Data collection method

Interview: from a paper questionnaire with double data entry. Clinical examinations: handwritten with double data entry. Clinical examinations: handwritten with double data entry.

Participant monitoring

Yes

Details on monitoring of participants

2 years

Links to administrative sources

No

## Promotion and access

### Promotion

Link to the document

<http://www.ncbi.nlm.nih.gov/pubmed/23768690>

Link to the document

<http://www.ncbi.nlm.nih.gov/pubmed/23349346>

Link to the document

<http://www.ncbi.nlm.nih.gov/pubmed/23329150>

## Access

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

Data may be used by academic teams: open to ancillary projects and replication of genetic studies. Data may not be used by industrial teams.

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only