

# COFRASA / GENERAC - Factors Favouring Aortic Stenosis

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## 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)

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### 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