

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 ≥ 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 ≥ 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