

CAVIAAR - Conservative Aortic Valve Surgery for Aortic Insufficiency and Aneurysms of the Aortic Root

Head :Lansac Emmanuel, Département de Pathologie cardiaque

Di Centa Isabelle, UNITÉ DE RECHERCHE CLINIQUE PARIS NORD GROUPE HOSPITALIER BICHAT CLAUDE BERNARD

Jourdain Cécile, DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE

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General

Identification

Detailed name Conservative Aortic Valve Surgery for Aortic Insufficiency and Aneurysms of the Aortic Root

Sign or acronym CAVIAAR

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation Accords CNIL, CPP

General Aspects

Medical area Cardiology

Health determinants Genetic

Keywords operative mortality, thromboembolic or haemorrhagic stroke, re-operation, placement, ascending aorta, valve endocarditis, Health episodes, valve, death

Scientific investigator(s) (Contact)

Name of the director Lansac

Surname Emmanuel

Address 75018 PARIS

Phone + 33 (0)6 64 23 38 25

Email caviaar@orange.fr

Unit Département de Pathologie cardiaque

Organization	Institut Mutualiste Montsouris
Name of the director	Di Centa
Surname	Isabelle
Address	75018 PARIS
Phone	+ 33 (0)6 08 15 12 92
Email	isabelle.di-centa@wanadoo.fr
Unit	UNITÉ DE RECHERCHE CLINIQUE PARIS NORD GROUPE HOSPITALIER BICHAT CLAUDE BERNARD
Organization	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

Name of the director	Jourdain
Surname	Cécile
Address	75011 PARIS
Phone	+ 33 (0)1 44 84 17 32
Email	cecile.jourdain@sls.aphp.fr
Unit	DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE
Organization	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

Collaborations

Participation in projects, networks and consortia	Yes
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Funding

Funding status	Public
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Details	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS
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Governance of the database

Sponsor(s) or organisation(s) responsible	APHP
Organisation status	Public

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 Yes

Details Performed at group level (clusters)

Additional information regarding sample selection. Inclusion method: Prospective

Database objective

Main objective

General objective: to demonstrate in a prospective open and multicentric cohort study that aortic valve sparing for patients with aortic root aneurysms and/or dystrophic aortic insufficiency is associated with a 45% increase of 3 year, 5 year, 10 year, 15 year and 20 year-survival rate without increased mortality or morbidity events when compared to mechanical valve replacement (surgical treatment reference). Morbidity and mortality is defined as the occurrence of at least one of the composite endpoint events: death, re-operation and/or re-hospitalisation for infection, bleeding event, thromboembolic event or heart failure

Secondary objectives:

- To evaluate and compare between both patient groups: the rate of immediate post-operation complications associated with a 3 year, 5 year, 10 year, 15 year and 20 year-survival rate without mortality or morbidity events when evaluated on composite criteria, the changes in quality of life during follow-up using a standardised questionnaire, validated by cardiac surgery, modified SF12 Questionnaire
- to evaluate the impact of a teaching programme for a new standardised surgical technique on morbidity and mortality from each investigating surgeon's learning curve and on long-term outcomes (programme combining theoretical and video-assisted surgical procedure training on heart anatomy, first patient surgical mentoring)
- To set predictive sonographic criteria: the feasibility of valve repair with promising

immediate and long-term postoperative results from early diagnosis of criteria composite outcome: To evaluate the sensitivity and specificity of ultrasound parameters, notably on the risk of reoperation and valvular complications - To assess the impact of clinical monitoring and imaging on operated patients with aortic root dystrophy in order to propose a post-operative care protocol that meets cost-benefit objectives

Inclusion criteria

- over 18 years of age; - aortic root aneurysms without aortic insufficiency or with dystrophic aortic insufficiency regardless of stage (including Marfan and bicuspid diseases), with indications for surgery conformed to American Heart Association or European Society of Cardiology guidelines or dystrophic aortic insufficiency (bicuspid or tricuspid valves) with no aortic root aneurysm with indications for surgery conformed to American Heart Association or European Society of Cardiology; - scheduled valve repair surgery with annuloplasty according to mechanical valve replacement CAVIAR study protocol; - Signed information letter and informed consent; - covered by social security insurance or access to CMU (beneficiary or assignee).

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 National

Detail of the geography area France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 05/2007

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 77:- 46 conservations valvulaires- 19 remplacements prothétiques mécaniques- 12 exclusions

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) Paper self-questionnaire
Face to face interview

Paraclinical data (detail) Imaging

Biological data (detail) Type of peri-operative and enrolment samples taken: full blood count, haemostasis, blood creatinine, INR, APTT and troponins During follow-up: INR if patient is under AVK

Presence of a biobank No

Health parameters studied Health event/morbidity
Health event/mortality
Quality of life/health perception

Procedures

Data collection method Self-administered questionnaire: Input from paper questionnaire (Manual input) with double data entry
Interview: Input from paper questionnaire (Manual input) with double data entry
Clinical Examinations: handwritten (Manual input) with double data entry
Biological Analysis: handwritten (Manual input) with double data entry

Participant monitoring Yes

Details on monitoring of participants Follow-up duration: 20 years

Links to administrative sources No

Promotion and access

Promotion

Link to the document <http://caviaar.com/de/Home/Presentations/Presentations-2014.html>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/?term=CAVIAAR>

Description List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay) To be decided if data may be used by academic teams To be decided if data may be used by industrial teams

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only